

EPA-APPROVED NEVADA NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES

Name of SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
AIR QUALITY IMPLEMENTATION PLAN FOR THE STATE OF NEVADA¹				
Supplement to the Nevada Division of Environmental Protection Portion of the Nevada "Infrastructure" SIP for the 2008 Ozone NAAQS: CAA § 110(a)(2)(D)(i)(I), Interstate Transport; excluding the cover letter to EPA Region 9 and attachments A and 2.	State-wide	3/25/2016	[Insert Federal Register citation] 2/3/2017.	Interstate transport supplement to the "Infrastructure" SIP for NDEP, Clark County and Washoe County for the 2008 8-hour ozone standard.

¹ The organization of this table generally follows from the organization of the State of Nevada's original 1972 SIP, which was divided into 12 sections. Nonattainment and maintenance plans, among other types of plans, are listed under Section 5 (Control Strategy). Lead SIPs and Small Business Stationary Source Technical and Environmental Compliance Assistance SIPs are listed after Section 12 followed by nonregulatory or quasi-regulatory statutory provisions approved into the SIP. Regulatory statutory provisions are listed in 40 CFR 52.1470(c).

■ 3. Section 52.1472 is amended by revising paragraph (h) to read as follows:

§ 52.1472 Approval status.

(h) *2008 8-hour ozone NAAQS*: The SIPs submitted on December 20, 2012 are partially disapproved for CAA elements 110(a)(2)(C), (D)(ii), and (J) for the NDEP and Washoe County portions of the Nevada SIP.

[FR Doc. 2017-02191 Filed 2-2-17; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA-HQ-OW-2016-0012; FRL-9958-40-OW]

RIN 2040-AF60

Aquatic Life Criteria for Cadmium in Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is establishing a federal Clean Water Act (CWA) aquatic life criterion for freshwaters under the state of Oregon's jurisdiction, to protect aquatic life from the effects of exposure to harmful levels of cadmium. In 2013, EPA determined that the freshwater acute cadmium criterion and freshwater acute and chronic copper criteria that Oregon adopted in 2004 did not meet CWA requirements to protect aquatic

life in the state. Since that time, the state adopted revised criteria for copper (which EPA is approving in parallel with this final rulemaking), but has not adopted a revised acute criterion for cadmium and thus EPA is establishing a federal freshwater acute criterion for cadmium that takes into account the best available science, EPA policies, guidance and legal requirements, to protect aquatic life uses in Oregon. **DATES:** This final rule is effective on March 6, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2016-0012. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Erica Fleisig, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 566-1057; email address: fleisig.eric@epa.gov.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

- I. General Information
 - A. Does this action apply to me?
 - B. How did EPA develop this final rule?
- II. Background

- A. Statutory and Regulatory Background
- B. EPA's Actions on Oregon's Freshwater Copper and Cadmium Criteria
- C. General Recommended Approach for Deriving Aquatic Life Criteria
- III. Freshwater Cadmium Aquatic Life Criteria
 - A. EPA's National Recommended Cadmium Criteria
 - B. Final Acute Cadmium Criterion for Oregon's Freshwaters
 - C. Additional Considerations for Calculation of Site-Dependent Cadmium Criteria
- IV. Implementation of Final Cadmium Criterion in Oregon
- V. Critical Low-Flows and Mixing Zones
- VI. Endangered Species Act
- VII. Applicability of Criteria
- VIII. Alternative Regulatory Approaches and Implementation Mechanisms
 - A. Designating Uses
 - B. Site-Specific Criteria
 - C. Variances
 - D. Compliance Schedules
- IX. Economic Analysis
 - A. Identifying Affected Entities
 - B. Method for Estimating Costs
 - C. Results
- X. Statutory and Executive Order Reviews
 - A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132 (Federalism)
 - F. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)
 - G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)
 - H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)
 - I. National Technology Transfer and Advancement Act of 1995

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)
K. Congressional Review Act (CRA)

At higher concentrations, cadmium can be toxic to aquatic life. Sources of elevated cadmium in the environment include coal combustion, mining, electroplating, iron and steel production, and use of pigments, fertilizers and pesticides. Industrial facilities, stormwater management districts, or publicly owned treatment works (POTWs) that discharge pollutants to freshwaters of the United States under the state of Oregon's

jurisdiction could be indirectly affected by this rulemaking, because federal water quality standards (WQS) promulgated by EPA are applicable to CWA regulatory programs, such as National Pollutant Discharge Elimination System (NPDES) permitting. Citizens concerned with water quality in Oregon could also be interested in this rulemaking. Categories and entities that could potentially be affected include the following:

I. General Information

A. Does this action apply to me?

Cadmium naturally occurs at low levels in surface waters, but anthropogenic activities can increase levels of cadmium in the environment.

Category	Examples of potentially affected entities
Industry	Industrial facilities discharging pollutants to freshwaters of the United States in Oregon.
Municipalities	Publicly owned treatment works or other facilities discharging pollutants to freshwaters of the United States in Oregon.
Stormwater Management Districts	Entities responsible for managing stormwater runoff in the state of Oregon.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. Any parties or entities who depend upon or contribute to the water quality of Oregon's waters could be indirectly affected by this rule. To determine whether your facility or activities could be indirectly affected by this action, you should carefully examine this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How did EPA develop this final rule?

In developing this final rule, EPA carefully considered the public comments and feedback received from interested parties. EPA originally provided a 45-day public comment period after publishing the proposed rule in the **Federal Register** on April 18, 2016.¹ In addition, EPA held two public hearings on May 16 and 17, 2016, to provide clarification on the contents of the proposed rule and accept verbal public comments.

Fourteen organizations and individuals submitted comments on a range of issues prior to the close of the public comment period on June 2, 2016. Some comments addressed issues beyond the scope of the rulemaking, and thus EPA did not consider them in finalizing this rule. In each section of this preamble, EPA discusses certain public comments so that the public is aware of the Agency's position. For a full response to these and all other comments, see EPA's Response to

Comments document in the official public docket.

II. Background

A. Statutory and Regulatory Background

CWA section 101(a)(2) establishes as a national goal "wherever attainable . . . water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water. . . ." These are commonly referred to as the "fishable/swimmable" goals of the CWA.

CWA section 303(c) (33 U.S.C. 1313(c)) directs states to adopt WQS for their waters subject to the CWA. CWA section 303(c)(2)(A) and EPA's implementing regulations at 40 CFR part 131 require, among other things, that a state's WQS specify appropriate designated uses of the waters, and water quality criteria that protect those uses. EPA's regulations at 40 CFR 131.11(a)(1) provide that "[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive use." In addition, 40 CFR 131.10(b) provides that "[i]n designating uses of a water body and the appropriate criteria for those uses, the [s]tate shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."

States are required to review applicable WQS at least once every three years and, if appropriate, revise or adopt new standards (CWA section 303(c)(1)). Any new or revised WQS must be submitted to EPA for review

and approval or disapproval (CWA section 303(c)(2)(A) and (c)(3)). If EPA disapproves a state's new or revised WQS, the CWA provides the state 90 days to adopt a revised WQS that meets CWA requirements, and if it fails to do so, EPA shall promptly propose and then within 90 days promulgate such standard unless EPA approves a state replacement WQS first (CWA section 303(c)(3) and (c)(4)(A)). CWA section 303(c)(4)(B) authorizes the Administrator to determine that a new or revised standard is needed to meet CWA requirements. Upon making such a determination, the CWA specifies that EPA shall promptly propose, and then within 90 days promulgate, any such new or revised standard unless prior to such promulgation, the state has adopted a revised or new WQS that EPA determines to be in accordance with the CWA.

Under CWA section 304(a), EPA periodically publishes criteria recommendations for states to consider when adopting water quality criteria for particular pollutants to meet the CWA section 101(a)(2) goal uses. In establishing criteria, states should establish numeric water quality criteria based on EPA's CWA section 304(a) criteria, section 304(a) criteria modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)). In all cases criteria must be sufficient to protect the designated use and be based on sound scientific rationale (40 CFR 131.11(a)(1)).

B. EPA's Actions on Oregon's Freshwater Copper and Cadmium Criteria

As discussed in the preamble to EPA's proposed rule (81 FR 22555; April 18, 2016), EPA disapproved several of Oregon's revised aquatic life criteria

¹ See Aquatic Life Criteria for Copper and Cadmium in Oregon: Proposed Rule, 81 FR 22555, April 18, 2016.

under CWA 303(c), including an acute cadmium freshwater criterion, and acute and chronic freshwater copper criteria that the National Marine Fisheries Service (NMFS) concluded would jeopardize endangered species in Oregon in its biological opinion dated August 14, 2012.^{2,3} On November 14, 2016, Oregon submitted revised freshwater copper criteria to EPA for review under CWA section 303(c). In parallel with this final rule, EPA is taking action under CWA 303(c) to approve the freshwater copper aquatic life criteria submitted by Oregon. Oregon did not adopt a revised acute cadmium criterion, however, therefore EPA is finalizing the freshwater acute cadmium criterion in this rule in accordance with CWA section 303(c)(3) and (c)(4) requirements.

C. General Recommended Approach for Deriving Aquatic Life Criteria

As discussed in the preamble to the 2016 proposed rule (81 FR 22555), to derive criteria for the protection of aquatic life, EPA follows its *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (referred to as the “1985 Guidelines”).⁴ These guidelines describe an objective way to estimate the highest concentration of a substance in water that will not present a significant risk to the aquatic organisms in the water.

Numeric criteria derived using EPA’s 1985 Guidelines are expressed as short-term (acute) and long-term (chronic) values. The combination of a criteria maximum concentration (CMC), a one-hour average value, and a criteria continuous concentration (CCC), a four-day average value, protects aquatic life from acute and chronic toxicity, respectively. Neither value is to be exceeded more than once in three years. EPA selected the CMC’s one-hour averaging period because high concentrations of certain pollutants can cause death in one to three hours, and

selected the CCC’s four-day averaging period to prevent increased adverse effects on sensitive life stages. EPA based the once every three years exceedance frequency recommendation on the ability of aquatic ecosystems to recover from the exceedances (when the average concentration over the duration of the averaging period is above the CCC or the CMC).⁵

Because fresh and salt waters have different chemical compositions and different species assemblages, it is necessary to derive separate acute and chronic criteria for fresh and salt waters. Additionally, criteria may be based on certain water characteristics (e.g., pH, temperature, hardness, dissolved organic carbon (DOC), etc.) because water chemistry can influence a pollutant’s bioavailability and toxicity. For metals in particular, EPA recommends expressing the criteria as functions of chemical constituents of the water, because those constituents can form complexes with metals and render the metals biologically unavailable, or compete with metals for binding sites on aquatic organisms. Additionally, in 1995, EPA recommended that criteria for metals be expressed as dissolved (rather than total) metal concentrations, because the concentration of dissolved metal better approximates the toxic fraction.⁶

III. Freshwater Cadmium Aquatic Life Criteria

A. EPA’s National Recommended Cadmium Criteria

Water hardness (determined by the presence of calcium and magnesium ions, and expressed as calcium carbonate, CaCO₃) affects the toxicity of cadmium, as calcium and magnesium ions compete with cadmium for binding sites on aquatic organisms’ gills. Organisms show more sensitivity to cadmium in lower hardness (soft) water than in hard water. EPA therefore expresses the national 304(a) recommended acute and chronic cadmium criteria as functions of water hardness.

On March 30, 2016, EPA announced publication of final updated 304(a) national recommended aquatic life criteria for cadmium.⁷ The 2016 cadmium 304(a) criteria reflect the best available science, including the results of laboratory aquatic toxicity tests for 75 new species. EPA lowered the updated 304(a) recommended freshwater acute cadmium criterion to protect commercially and recreationally important salmonids, consistent with EPA’s 1985 Guidelines. In addition, EPA revised the effect of total hardness on cadmium toxicity using the newly acquired data.

B. Final Acute Cadmium Criterion for Oregon’s Freshwaters

To protect aquatic life in Oregon’s freshwaters from acute toxic effects from cadmium, EPA is promulgating the one-hour average CMC of $e^{(0.9789 \times \ln(\text{hardness}) - 3.866)} \times \text{CF}$ (µg/L, dissolved), not to be exceeded more than once every three years. “CF” refers to the conversion factor and is used to convert the total recoverable concentration to a dissolved concentration, consistent with EPA’s policy on criteria for metals. The equation for the acute cadmium CF is $\text{CF} = 1.136672 - [(\ln \text{hardness}) \times (0.041838)]$. This is the same freshwater acute cadmium criterion (and associated CF) as in EPA’s final 2016 national updated 304(a) recommended cadmium criteria. The (ln hardness) term in both the CMC equation and the CF equation is the natural logarithm of the ambient water hardness in mg/L (CaCO₃). Commenters were generally supportive of EPA’s proposal to apply the final 2016 national 304(a) recommended acute cadmium criterion (and associated CF) to freshwaters in Oregon.

Where site-specific hardness data are unavailable, EPA is establishing default hardness concentrations (as CaCO₃), based on the 10th percentile of existing hardness concentrations in waters within each of the nine Level III ecoregions in Oregon. These ecoregion-specific default hardness concentrations are set forth in Table 2 in the final regulatory text for § 131.46.

To determine the default hardness concentrations, EPA used 10th percentile hardness estimates from Table 4 in USEPA’s *Recommended Estimates for Missing Water Quality Parameters for Application in EPA’s Biotic Ligand Model*, February 16, 2016

² See USEPA. 2013. *EPA Clean Water Act 303(c) Determinations On Oregon’s New and Revised Aquatic Life Toxic Criteria Submitted on July 8, 2004, and as Amended by Oregon’s April 23, 2007 and July 21, 2011 Submissions*. Page 46.

³ The NMFS biological opinion contained Reasonable and Prudent Alternatives (RPAs) that would avoid the likelihood of jeopardy to the species. For acute cadmium, the RPA specified a process for deriving revised freshwater criteria.

⁴ USEPA. 1985. *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*. U.S. Environmental Protection Agency, Office of Research and Development, Duluth, MN, Narragansett, RI, Corvallis, OR. PB85-227049. <https://www.epa.gov/wqc/guidelines-deriving-numerical-national-water-quality-criteria-protection-aquatic-organisms-and>.

⁵ See USEPA, 1985. Pages 5–7.

⁶ *Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States’ Compliance—Revision of Metals Criteria*, May 4, 1995, 60 FR 22229.

⁷ USEPA. 2016. *Aquatic Life Ambient Water Quality Criteria: Cadmium—2016*. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA-820-R-16-002.

(EPA 820-R-15-106).⁸ EPA elected to rely on the dataset⁹ that formed the basis for the recommendations in EPA's peer-reviewed *Missing Parameters* document to determine the proposed and final defaults for Oregon. While not the only acceptable dataset, the dataset that EPA used in its *Missing Parameters* document is robust and publicly available, and is therefore a reasonable source of data to determine scientifically defensible and protective default hardness concentrations for the acute cadmium criterion. Although EPA is promulgating these default hardness values to use in the absence of ambient hardness data, EPA strongly recommends that Oregon collect sufficiently representative ambient hardness data to determine the appropriate acute cadmium criterion for a site.

Some commenters were in favor of EPA's decision to include default input parameters, while others were critical of this approach. Specifically related to EPA's proposal of a default hardness value for use with the acute cadmium criterion, some commenters argued that EPA's proposal of a default hardness value of 25 mg/L was overly conservative because it is below the lowest existing 10th percentile ecoregional hardness concentration in Oregon. EPA maintains that it is important to include default values for hardness to provide clarity to NPDES permit writers and water body assessors as to the applicable acute cadmium criterion at the site when there are insufficient ambient hardness data to adequately characterize the site. The default hardness of 25 mg/L that EPA proposed in its April 18, 2016 proposed rule (81 FR 22555) is protective and consistent with Oregon's application of a default hardness concentration of 25 mg/L if no hardness data are available to calculate hardness-dependent metals criteria.¹⁰ However, EPA recognizes that hardness concentrations vary throughout the state, and using more refined hardness defaults based on ecoregion-specific data, rather than a single statewide default hardness value, would also result in protective criteria

in the absence of ambient hardness data. Therefore, in this rulemaking EPA is finalizing different default hardness concentrations that correspond to the 10th percentile of ambient hardness data from each of the nine ecoregions in Oregon.

Consistent with EPA guidance, the hardness default does not represent a "hardness floor" for the ecoregion; rather, a site's actual ambient water hardness should be used to calculate the criterion when sufficiently representative hardness data are available, even if ambient hardness is below the default hardness concentration.¹¹

C. Additional Considerations for Calculation of Site-Dependent Cadmium Criteria

Commenters requested that EPA provide additional specificity on the minimum number of samples required to adequately capture temporal and spatial variability at a site, and site selection considerations. While many of these comments were with respect to copper criteria calculations, EPA agrees that these are important considerations for cadmium as well. In response to these comments, EPA is providing the following recommendations.

The number of samples needed to characterize site variability depends on several characteristics of the site. The water quality characteristics that determine the bioavailability of metals, including cadmium, can vary widely in both space and time, changing with biological activity, flow, geology, human activities, watershed landscape, and other features of the water body. For the state to ensure that the criteria are adequately protective of the most bioavailable conditions at the site through time, the state should apply appropriate methods to evaluate how a site's water quality conditions are expected to vary temporally, and ensure that adequate monitoring is in place to capture the variability across the site and through time.

The state should first demonstrate that the hardness concentrations used in the calculations are not biased toward less bioavailable conditions for cadmium by evaluating the hardness data and resultant acute cadmium criteria that are calculated over time for different flows and seasons. The state should use appropriate analytical methods, such as a Monte Carlo¹²

simulation or another analytical tool, to determine if the monitoring methods are sufficient to capture the temporal trends, and the resultant calculated criteria are adequate to represent the most bioavailable conditions over time at the site.

Oregon should consider the following when defining a site to which to apply criteria for cadmium: (1) Metals are generally persistent, so calculating the criterion using input parameter values from a location at or near the discharge point could result in a criterion that is not protective of areas that are outside of that location, and (2) as the size of a site increases, the spatial and temporal variability is likely to increase; thus, more water samples may be required to adequately characterize the entire site.¹³ Additionally, pursuant to 40 CFR 131.10(b), Oregon must consider downstream WQS when calculating a protective criterion in upstream waters.

Substantial changes in a site's ambient hardness will likely affect the bioavailability of and the relevant criterion for cadmium at that site. In addition, with regular monitoring and a robust, site-specific dataset, criteria can be developed that more accurately reflect site conditions than criteria set using default values or limited data sets. Therefore, EPA recommends that Oregon periodically revisit each water body's cadmium criterion and re-run the hardness equation when changes in water chemistry are evident or suspected at a site, and also as additional monitoring data become available.

When Oregon calculates cadmium criteria, to promote transparency and ensure predictable and repeatable outcomes, EPA recommends that the state make each site's ambient hardness data used in the cadmium criteria calculations, resultant numeric criteria, and the geographic extent of the site publicly available on the state's Web site.

IV. Implementation of Final Cadmium Criterion in Oregon

Because organisms are more sensitive to cadmium when hardness is low, Oregon should ensure that sufficiently representative ambient hardness data are collected to have confidence that critical conditions in the water body are

probability of identifying the most bioavailable time period for a series of monitoring scenarios. From such an analysis, the state can select the appropriate monitoring regime.

¹³ USEPA. 1994. *Interim Guidance on Determination and Use of Water-Effect Ratios for Metals*. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA-823-B-94-001. February 1994.

⁸ For a map of Level III ecoregions in the continental United States, see: <https://www.epa.gov/eco-research/level-iii-and-iv-ecoregions-continental-united-states>.

⁹ Data came from several water quality databases including the Storage and Retrieval Data System, National Waters Information System (NWIS), Wadeable Stream Assessment, and National River and Stream Assessment (NRSA) database.

¹⁰ Oregon Department of Environmental Quality. 2014. *Methodology for Oregon's 2012 Water Quality Report and List of Water Quality Limited Waters (Pursuant to Clean Water Act Sections 303(d) and 305(b) and OAR 340-041-0046)*. Pages 76-77.

¹¹ USEPA. 2002. *National Recommended Water Quality Criteria: 2002*. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA-822-R-02-047.

¹² Given sufficient data, Monte Carlo simulation or equivalent analysis can be used to determine the

being adequately captured. When setting Water Quality-Based Effluent Limitations (WQBELs) for cadmium, Oregon should determine hardness values that represent the receiving water both upstream of and below the point of discharge under critical conditions (*i.e.*, low hardness) when cadmium bioavailability is expected to be greater, such that the resulting criteria calculations, reasonable potential analyses, and any effluent limitations will be protective of the entire site at critical conditions. EPA's NPDES Permit Writers' Manual describes the importance of determining effluent and receiving water critical conditions, because if a discharge is controlled so that it does not cause water quality criteria to be exceeded in the receiving water under critical conditions, then water quality criteria should be attained under all other conditions.¹⁴ The same principle holds for developing a TMDL target.

For transparency for the public, EPA recommends that Oregon describe in its NPDES permit factsheets how the numeric criteria were calculated and used to determine reasonable potential and derive WQBELs. Similarly for TMDLs, EPA recommends that Oregon describe in the TMDL document how the numeric criteria were calculated and used to determine TMDL targets. In the assessment and listing context, EPA recommends that Oregon describe in its integrated reports how it calculated numeric criteria to which it compared ambient cadmium concentrations.

V. Critical Low-Flows and Mixing Zones

To ensure that the criteria are applied appropriately to protect Oregon's aquatic life uses, EPA is establishing critical low-flow values for Oregon to use in calculating the available dilution for the purposes of determining the need for and establishing WQBELs in NPDES permits. Dilution is one of the primary mechanisms by which the concentrations of contaminants in effluent discharges are reduced following their introduction into a receiving water. Low flows can exacerbate the effects of effluent discharges because, during a low-flow event, there is less water available for dilution, resulting in higher instream pollutant concentrations. If criteria are implemented using inappropriate critical low-flow values (*i.e.*, values that are too high), the resulting ambient

concentrations could exceed criteria when low flows occur.¹⁵

EPA's March 1991 *Technical Support Document for Water Quality-based Toxics Control* recommends two methods for calculating acceptable critical low-flow values: The traditional hydrologically based method developed by the USGS and a biologically based method developed by EPA.¹⁶ The hydrologically based critical low-flow value is determined statistically using probability and extreme values, while the biologically based critical low-flow is determined empirically using the specific duration and frequency associated with the criterion.

For the freshwater acute cadmium criterion, EPA establishes the following critical low-flow values: 1Q10 or 1B3. Using the hydrologically based method, the 1Q10 represents the lowest one-day average flow event expected to occur once every ten years, on average. Using the biologically based method, 1B3 represents the lowest one-day average flow event expected to occur once every three years, on average.¹⁷

The criterion in this final rule applies at the point of discharge unless Oregon authorizes a mixing zone. Where Oregon authorizes a mixing zone, the criterion applies at the locations allowed by the mixing zone (*i.e.*, the CMC would apply at the defined boundary of the acute mixing zone).¹⁸

One commenter argued that EPA's proposed critical low-flow provisions were unnecessary, asserting that Oregon already has such provisions. Currently Oregon's implementation methods for low-flows are in non-binding guidance. Specifying the appropriate low-flow provisions in regulation will provide added clarity, and ensure that the acute cadmium criterion is implemented in such a way that designated uses are protected.

VI. Endangered Species Act

As noted in the 2016 proposed rule, the NMFS 2012 biological opinion concluded that the freshwater acute cadmium criterion that Oregon adopted in 2004 would jeopardize the continued existence of specific endangered species and their critical habitat in Oregon. The

opinion also contained a reasonable and prudent alternative (RPA) for cadmium that would avoid the likelihood of jeopardy to endangered species in Oregon.

EPA has determined that the acute cadmium criterion being finalized in this rulemaking is consistent with the RPA for acute cadmium as contained in the NMFS 2012 biological opinion. Therefore, as finalized, the acute cadmium criterion for Oregon is sufficiently protective of threatened and endangered species in state waters and avoids the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. EPA's RPA analysis for the acute cadmium criterion is contained in the docket for this rule.

VII. Applicability of Criteria

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their navigable waters (CWA section 303(a)–(c)). Although EPA is establishing an acute cadmium criterion for Oregon's freshwaters to remedy EPA's 2013 disapproval of Oregon's 2004 criteria, Oregon continues to have the option to adopt and submit to EPA an acute cadmium criterion for the state's freshwaters consistent with CWA section 303(c) and EPA's implementing regulations at 40 CFR part 131.

In its April 18, 2016, proposed rule, EPA proposed that if Oregon adopted and submitted freshwater cadmium and/or copper aquatic life criteria after EPA's finalization of the freshwater acute cadmium criterion and freshwater acute and chronic copper criteria, then once EPA approved Oregon's WQS, those EPA-approved criteria in Oregon's WQS would automatically become solely effective for CWA purposes and EPA's promulgated criteria would no longer apply. EPA did not receive any comments on this provision as it relates to copper and cadmium criteria for Oregon, and this provision is moot with respect to copper since Oregon adopted revised freshwater copper criteria (which EPA is approving in parallel with this final acute cadmium criterion rulemaking). However, upon further consideration of comments received on other proposed rules where EPA proposed a similar provision, EPA decided not to finalize this provision. Pursuant to 40 CFR 131.21(c), EPA's federally promulgated WQS are and will be applicable for purposes of the CWA until EPA withdraws those federally promulgated WQS. EPA would expeditiously undertake such a rulemaking to withdraw the federal

¹⁴ USEPA. 2010. *NPDES Permit Writers' Manual*. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA-833-K-10-001. September 2010.

¹⁵ USEPA. 2014. *Water Quality Standards Handbook-Chapter 5: General Policies*. U.S. Environmental Protection Agency, Office of Water. Washington, DC EPA-820-B-14&-004. <http://www.epa.gov/sites/production/files/2014-09/documents/handbook-chapter5.pdf>.

¹⁶ USEPA. 1991. *Technical Support Document For Water Quality-based Toxics Control*. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA/505/2-90-001. <http://www3.epa.gov/npdes/pubs/owm0264.pdf>.

¹⁷ See USEPA, 2014.

¹⁸ See USEPA, 1991.

acute cadmium criterion if and when Oregon adopts and EPA approves a corresponding criterion that meets the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131.

VIII. Alternative Regulatory Approaches and Implementation Mechanisms

Oregon has considerable discretion to implement the acute cadmium aquatic life criterion through various water quality control programs. Among other things, EPA's regulations: (1) Specify how states and authorized tribes establish, modify, or remove designated uses; (2) specify the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions; (3) authorize states and authorized tribes to adopt WQS variances to provide time to achieve the applicable WQS; and (4) allow states and authorized tribes to include compliance schedules in NPDES permits. Each of these approaches are discussed in this section.

A. Designating Uses

EPA's final acute cadmium criterion applies to freshwaters in Oregon where the protection of fish and aquatic life is a designated use (see Oregon Administrative Rules at 340-041-8033, Table 30). The federal regulations at 40 CFR 131.10 specify how states and authorized tribes establish, modify or remove designated uses for their waters. If Oregon removes designated uses such that no fish or aquatic life uses apply to any particular water body affected by this rule and adopts the highest attainable use,¹⁹ and EPA finds that removal to be consistent with CWA section 303(c) and EPA's implementing regulations at 40 CFR part 131, then the federal acute cadmium criterion would no longer apply to that water body. Instead, any criterion associated with the newly designated highest attainable use would apply to that water body.

B. Site-Specific Criteria

EPA's regulations at 40 CFR 131.11 specify requirements for establishing criteria to protect designated uses, including criteria modified to reflect

site-specific conditions. In the context of this rulemaking, a site-specific criterion (SSC) is an alternative value to the federal freshwater acute cadmium criterion that would be applied on a watershed, area-wide, or water body-specific basis that meets the regulatory test of protecting the designated use, being scientifically defensible, and ensuring the protection and maintenance of downstream WQS. A SSC may be more or less stringent than the otherwise applicable federal criterion. A SSC may be appropriate when further scientific data and analyses can bring added precision to express the concentration of cadmium that protects the aquatic life-related designated use in a particular water body. As discussed earlier, if Oregon adopts and EPA approves site-specific criteria that fully meet the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131, EPA will undertake a rulemaking to withdraw the corresponding federal criterion.

C. Variances

40 CFR part 131 defines WQS variances at 131.3(o) as time-limited designated uses and supporting criteria for a specific pollutant(s) or water quality parameter(s) that reflect the highest attainable conditions during the term of the WQS variances. WQS variances adopted in accordance with 40 CFR part 131 allow states and authorized tribes to address water quality challenges in a transparent and predictable way. Variances help states and authorized tribes focus on making incremental progress in improving water quality, rather than pursuing a downgrade of the underlying water quality goals through a designated use change, when the designated use is not attainable throughout the term of the variance due to one of the factors listed in 40 CFR 131.14. Oregon has sufficient authority to use variances when implementing the final acute cadmium criterion, as long as such variances are adopted consistent with 40 CFR 131.14, and submitted to EPA for review under CWA section 303(c).

D. Compliance Schedules

EPA's regulations at 40 CFR 122.47 provide the requirements when states and authorized tribes wish to include permit compliance schedules in their NPDES permits if dischargers need additional time to meet their WQBELs based on the applicable WQS. EPA's updated regulations at 40 CFR 131.15 require any state or authorized tribe wishing to use permit compliance schedules to also include provisions

authorizing the use of permit compliance schedules after appropriate public involvement to ensure that a decision to allow permit compliance schedules derives from and complies with the applicable WQS. (80 FR 51022, August 21, 2015). Oregon may use its EPA-approved regulation authorizing the use of permit compliance schedules (see OAR 340-041-0061), consistent with 40 CFR 131.15, to grant compliance schedules, as appropriate, for WQBELs based on the federal acute cadmium criterion. That state regulation is not affected by this final rule.

IX. Economic Analysis

Although EPA's final acute cadmium criterion itself will not impose any direct requirements on entities, this criterion may ultimately serve as a basis for development of new or revised NPDES permit limits. Oregon has NPDES permitting authority, and retains considerable discretion in implementing standards. Still, to best inform the public of the potential impacts of this rule, EPA evaluated the potential costs associated with state implementation of EPA's final criterion. This analysis is documented in *Economic Analysis for the Final Rule: Aquatic Life Criteria for Cadmium in Oregon*, which can be found in the record for this rulemaking.

For the economic analysis, EPA assumed the baseline to be full implementation of currently approved existing aquatic life criteria (*i.e.*, "baseline criteria") and then estimated the incremental impacts for compliance with the final cadmium criterion in this rule. For point source costs, any NPDES-permitted facility that discharges cadmium could potentially incur compliance costs. The types of affected facilities could include industrial facilities and publicly owned treatment works (POTWs) discharging sanitary wastewater to surface waters (*i.e.*, point sources). EPA expects that dischargers would use similar process and treatment controls to come into compliance with the final cadmium criterion as they would to comply with Oregon's baseline criteria.

EPA did not estimate the potential for costs to stormwater or nonpoint sources such as agricultural runoff. EPA recognizes that Oregon may require controls for nonpoint sources; however, it is difficult to model and evaluate the potential cost impacts of this rule to those sources because they are intermittent, variable, and occur under hydrologic or climatic conditions associated with precipitation events. Also, baseline total maximum daily loads (TMDLs) for waters with baseline impairment for cadmium have not yet

¹⁹ Highest attainable use is the modified aquatic life, wildlife, or recreation use that is both closest to the uses specified in section 101(a)(2) of the Act and attainable, based on the evaluation of the factor(s) in § 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the Act and sub-categories of such a use are not attainable (see 40 CFR 131.3(m)).

been developed; therefore, determining which waters would not achieve standards based on the final aquatic life criterion after complying with existing (baseline) regulations and policies may not be possible.

A. Identifying Affected Entities

For identifying new criteria values for the purposes of estimating cost incremental to costs to achieve the existing baseline criteria, EPA developed hypothetical applications of the final cadmium criterion using conservative estimates for hardness. The criteria that EPA calculated for the economic analysis are likely different from and possibly lower (more stringent) than the actual criteria applications that Oregon would calculate using ambient data from each water body. As described earlier in this final rule, EPA recommends that Oregon collect sufficiently representative ambient data to calculate the most accurate and protective cadmium criteria by site.

Using the criteria calculated for the cost analysis, EPA identified 12 point source facilities with sufficient data for evaluation²⁰ that could potentially be affected by the rule—all are major dischargers. Major discharge facilities are typically those that discharge more than 1 million gallons per day (mgd). Of these potentially affected facilities, 10 are POTWs (municipals) and two are industrial dischargers. EPA did not include facilities covered by general permits in its analysis because none of the general permits reviewed include specific effluent limits or monitoring requirements for cadmium except for two industrial stormwater general permits that include monitoring requirements for cadmium, but no effluent limits. See the Economic Analysis for more details.

B. Method for Estimating Costs

For facilities with available data, EPA evaluated existing baseline permit conditions, reasonable potential to exceed estimates of the aquatic life criteria based on the final rule, and potential to exceed projected effluent limitations based on available effluent

²⁰EPA initially used ICIS-NPDES to identify facilities in Oregon whose NPDES permits contain effluent limitations and/or monitoring requirements for cadmium. There were neither sufficient nor adequate data available to evaluate those facilities. Therefore, EPA obtained monitoring data from the Oregon Department of Environmental Quality. EPA excluded biosolids data, facilities with ocean discharges (*i.e.*, not freshwater), facilities where all reported results were non-detect, facilities with less than three data points, and others where there were insufficient or inadequate data to perform the analysis. EPA obtained facility-specific information from NPDES permits and fact sheets.

monitoring data. There was no reasonable potential to exceed the final acute cadmium criterion.

If the final criterion resulted in an incremental increase in impaired waters, resulting in the need for TMDL development, there could also be some costs to nonpoint sources of cadmium. Using available ambient monitoring data, EPA compared cadmium concentrations to the baseline and final criteria, identifying waterbodies that may be incrementally impaired (*i.e.*, impaired under the final criteria but not under the baseline). EPA did not identify the potential for incremental impairment due to the final acute cadmium criterion.

C. Results

As discussed above, EPA determined there are no point or nonpoint source costs associated with the acute cadmium criterion in this final rule. None of the dischargers for which monitoring data are available have a reasonable potential to exceed the final criterion. Therefore, EPA estimates that point source dischargers will not incur annual costs to comply with the final acute cadmium criterion. Additionally, based on available monitoring data, EPA did not identify any location that would be incrementally impaired under the final criterion. Therefore, EPA did not attribute any cost to nonpoint sources for compliance with the final acute cadmium criterion.

X. Statutory and Executive Order Reviews

A. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, *Economic Analysis for the Final Rule: Aquatic Life Criteria for Cadmium in Oregon*, is summarized in section IX of the preamble and is available in the docket.

B. Paperwork Reduction Act

This action does not impose any direct new information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Actions to implement these WQS could entail additional paperwork burden. Burden is defined at 5 CFR

1320.3(b). This action does not include any information collection, reporting, or record-keeping requirements.

C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. EPA-promulgated standards are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, EPA's promulgation of WQS establishes standards that the state implements through the NPDES permit process. The state has discretion in developing discharge limits, as needed to meet the standards. As a result of this action, the State of Oregon will need to ensure that permits it issues include any limitations on discharges necessary to comply with the standards established in the final rule. In doing so, the state will have a number of choices associated with permit writing. While Oregon's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA's action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing.

D. Unfunded Mandates Reform Act

This action contains no federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. As these water quality criteria are not self-implementing, EPA's action imposes no enforceable duty on any state, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that could significantly or uniquely affect small governments.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It 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. This rule does not alter Oregon's considerable discretion in implementing these WQS, nor will it preclude Oregon from adopting WQS in the future that EPA concludes meet the requirements of the CWA, which will eliminate the need for federal standards. Thus, Executive Order 13132 does not apply to this action.

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 rule does not impose substantial direct compliance costs on federally recognized tribal governments, nor does it substantially affect the relationship between the federal government and tribes, or the distribution of power and responsibilities between the federal government and tribes. Thus, Executive Order 13175 does not apply to this action.

Many tribes in the Pacific Northwest hold reserved rights to take fish for subsistence, ceremonial, religious, and commercial purposes. EPA developed the criteria in this final rule to protect aquatic life in Oregon from the effects of exposure to harmful levels of cadmium. Protecting the health of fish in Oregon will, therefore, support tribal reserved fishing rights, including treaty-reserved rights, where such rights apply in waters under state jurisdiction.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with tribal officials during the development of this action. On November 23, 2015, EPA sent a letter to tribal leaders in Oregon

offering to consult on the proposed cadmium criterion in this rule. On December 15, 2015, EPA held a conference call with tribal water quality technical contacts to explain EPA's proposed action and timeline. Formal consultation on the proposed action was not requested by any of the tribes.

G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)

This rule is not subject to Executive Order 13045, because it is not economically significant as defined in Executive Order 12866, and because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

This final rulemaking does not involve technical standards.

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

The human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. The criterion in this final rule will support the health and abundance of aquatic life in Oregon, and will therefore benefit all

communities that rely on Oregon's ecosystems.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and 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 a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 131

Environmental protection, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: January 10, 2017.

Gina McCarthy,
Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

- 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

- 2. Add § 131.46 to read as follows:

§ 131.46 Aquatic life criterion for cadmium in Oregon.

(a) *Scope.* This section promulgates an acute aquatic life criterion for cadmium in freshwaters in Oregon.

(b) *Criterion for cadmium in Oregon.* The aquatic life criterion in Table 1 applies to all freshwaters in Oregon where fish and aquatic life are a designated use.

TABLE 1—CADMIUM AQUATIC LIFE CRITERION FOR OREGON FRESHWATERS

Metal	CAS No.	Criterion Maximum Concentration (CMC) ³ (µg/L)
Cadmium ^{1,2}	7440439	$[e^{(0.9789 \times \ln(\text{hardness}) - 3.866)}] \times CF$ Where CF = $1.136672 - [(\ln \text{hardness}) \times (0.041838)]$.

¹ The criterion for cadmium is expressed as the dissolved metal concentration.

² CF is the conversion factor used to convert between the total recoverable and dissolved forms of cadmium. The term (ln hardness) in the CMC and the CF equation is the natural logarithm of the ambient hardness in mg/L (CaCO₃). The default hardness concentrations from the applicable ecoregion in Table 2 of paragraph (c) of this section shall be used to calculate cadmium criteria in the absence of sufficiently representative ambient hardness data.

³ The CMC is the highest allowable one-hour average instream concentration of cadmium. The CMC is not to be exceeded more than once every three years. The CMC is rounded to two significant figures.

(c) *Estimated Values To Calculate Cadmium Criteria.* The default inputs to calculate cadmium criteria in the absence of sufficiently representative ambient data are shown in Table 2.

TABLE 2—HARDNESS DEFAULTS WITHIN EACH LEVEL III ECOREGION IN OREGON

Level III ecoregion	Hardness mg/L)
1 Coast Range	34.12
3 Willamette Valley	32.39

TABLE 2—HARDNESS DEFAULTS WITHIN EACH LEVEL III ECOREGION IN OREGON—Continued

Level III ecoregion	Hardness mg/L)
4 Cascades	28.39

TABLE 2—HARDNESS DEFAULTS WITHIN EACH LEVEL III ECOREGION IN OREGON—Continued

Level III ecoregion	Hardness mg/L)
9 Eastern Cascades Slopes and Foothills	36.08
10 Columbia Plateau	58.82
11 Blue Mountains	43.49
12 Snake River Plain	123.5
78 Klamath Mountains	40.61
80 Northern Basin and Range ...	98.62

(d) *Applicability.* (1) The criterion in paragraph (b) of this section applies to freshwaters in Oregon where fish and aquatic life are a designated use, and applies concurrently with other applicable water quality criteria.

(2) The criterion established in this section is subject to Oregon’s general rules of applicability in the same way and to the same extent as are other federally promulgated and state-adopted numeric criteria when applied to freshwaters in Oregon where fish and aquatic life are a designated use.

(i) For all waters with mixing zone regulations or implementation procedures, the criterion applies at the appropriate locations within or at the boundary of the mixing zones and outside of the mixing zones; otherwise the criterion applies throughout the water body including at the end of any discharge pipe, conveyance or other discharge point within the water body.

(ii) The state shall not use a low flow value that is less stringent than the values listed below for waters suitable for the establishment of low flow return frequencies (*i.e.*, streams and rivers) when calculating the available dilution for the purposes of determining the need for and establishing Water Quality-Based Effluent Limitations in National Pollutant Discharge Elimination System permits:

Acute criteria (CMC)	1Q10 or 1B3
----------------------	-------------

Where:

1. 1Q10 is the lowest one-day average flow event expected to occur once every ten years, on average (determined hydrologically).
2. 1B3 is the lowest one-day average flow event expected to occur once every three years, on average (determined biologically).

[FR Doc. 2017–02283 Filed 2–2–17; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 102

RIN 0991–AC0

Annual Civil Monetary Penalties Inflation Adjustment

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalties in its regulations, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015.

DATES: This rule is effective February 3, 2017.

FOR FURTHER INFORMATION CONTACT: Andrea Brandon, Deputy Assistant Secretary for Grants and Acquisitions, Office of the Assistant Secretary for Financial Resources, Room 514–G, Hubert Humphrey Building, 200 Independence Avenue SW., Washington DC 20201; 202–690–6396; FAX 202–690–5405.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the “Act”), which is intended to improve the effectiveness of civil monetary penalties (“CMPs”) and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

The Department of Health and Human Services (HHS) lists the civil monetary penalties and the penalty amounts administered by all of its agencies in tabular form in 45 CFR 102.3.

II. Calculation of Adjustment

The annual inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each civil penalty was most recently established or modified. In the December 16, 2016, OMB Memorandum for the Heads of Executive Agencies and Departments, M–17–11, *Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*, OMB published the multiplier for

the required annual adjustment. The cost-of-living adjustment multiplier for 2017, based on the CPI–U for the month of October 2016, not seasonally adjusted, is 1.01636.

Using the 2017 multiplier, HHS adjusted all its applicable monetary penalties in 45 CFR 102.3.

III. Statutory and Executive Order Reviews

The 2015 Act Requires Federal Agencies To Publish Annual Penalty Inflation Adjustments Notwithstanding Section 553 of the Administrative Procedure Act

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Section 4 of the 2015 Act directs federal agencies to publish annual adjustments no later than January 15, 2017. In accordance with section 553 of the Administrative Procedure Act (APA), most rules are subject to notice and comment and are effective no earlier than 30 days after publication in the **Federal Register**. However, Section 4(b)(2) of the 2015 Act provides that each agency shall make the annual inflation adjustments “notwithstanding section 553” of the APA. According to OMB’s Memorandum M–17–11, *Memorandum of the Heads of Executive Departments and Agencies* (December 16, 2016) the phrase “notwithstanding section 553” means that “the public procedure the APA generally provides—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.” Consistent with the language of the 2015 Act and OMB’s implementation guidance, this rule is not subject to notice and an opportunity for public comment and will be effective immediately upon publication.

B. Review Under Procedural Statutes and Executive Orders

Pursuant to OMB Memorandum for the Heads of Executive Departments and Agencies, M–17–11, HHS has determined that making technical changes to the amount of civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive Orders that govern rulemaking procedures.

IV. Effective Date

This rule is effective February 3, 2017. The adjusted civil penalty amounts apply to civil penalties assessed on or after February 3, 2017, when the