and pests, Reporting and recordkeeping requirements.

Dated: May 4, 2017.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.681 is amended as follows:

■ a. In the table in paragraph (a) alphabetically add the following commodities: ''Apple, wet pomace''; ''Bushberry subgroup 13–07B''; ''Caneberry subgroup 13–07A''; ''Cherry subgroup 12–12A''; ''Fruit, pome, group 11–10''; ''Fruit, small vine climbing, except grape, subgroup 13–07E''; ''Pea and bean, dried shelled, except soybean, subgroup 6C''; ''Pea and bean, succulent shelled, subgroup 6B''; ''Peach subgroup 12–12B''; ''Plum, Prune, Dried''; ''Plum subgroup 12–12C''; ''Vegetable, legume, edible podded, subgroup 6A''.

■ b. Paragraph (b) is revised.

The additions and revision read as follows:

§ 180.681 Isofetamid; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Apple, wet pomace	2.0
Bushberry subgroup 13–07B	5.0
Caneberry subgroup 13–07A	4.0
* * * * *	
Cherry subgroup 12–12A	4.0
* * * * *	
Fruit, pome, group 11–10	0.60
* * * * *	
Fruit, small vine climbing, except grape, subgroup 13–07E	10.0
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	0.040
Pea and bean, succulent shelled, subgroup 6B	0.030
Peach subgroup 12–12B	3.0
Plum, Prune, Dried	1.50
Plum subgroup 12–12C	0.80
* * * * *	
Vegetable, legume, edible podded, subgroup 6A	1.50

(b) *Section 18 emergency exemptions.* [Reserved]

* * * * *

[FR Doc. 2017–12346 Filed 6–13–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 441

[EPA–HQ–OW–2014–0693; FRL–9957–10–OW]

RIN 2040–AF26

Effluent Limitations Guidelines and Standards for the Dental Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating technology-based pretreatment standards under the Clean Water Act to reduce discharges of mercury from dental offices into municipal sewage treatment plants known as publicly owned treatment works (POTWs). This final rule requires dental offices to use amalgam separators and two best management practices recommended by the American Dental Association (ADA). This final rule includes a provision to significantly reduce and streamline the oversight and reporting requirements in EPA's General Pretreatment Regulations that would otherwise apply as a result of this rulemaking. EPA expects compliance with this final rule will annually reduce the discharge of mercury by 5.1 tons as well as 5.3 tons of other metals found in waste dental amalgam to POTWs.

DATES: The final rule is effective on July 14, 2017. The compliance date, meaning the date that existing sources subject to the rule must comply with the standards in this rule is July 14, 2020. After the effective date of the rule, new sources subject to this rule must comply immediately with the standards in this rule. In accordance with 40 CFR part 23, this regulation shall be considered issued for purposes of judicial review at 1 p.m. Eastern time on June 28, 2017. Under section 509(b)(1) of the CWA, judicial review of this regulation can be had only by filing a petition for review in the U.S. Court of Appeals within 120 days after the regulation is considered issued for purposes of judicial review. Under section 509(b)(2), the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2014–0693. All documents in the docket are listed on the *https://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. This material can be viewed at the Water Docket in the EPA Docket Center, EPA/DC, EPA West William Jefferson Clinton Bldg., Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading room is 202–566–1744, and the telephone number for the Water Docket is 202–566–2426. Publicly available docket materials are available electronically through *http://www.regulations.gov.* A detailed record index, organized by subject, is available on EPA's Web site at *https://www.epa.gov/eg/dental-effluent-guidelines* .

FOR FURTHER INFORMATION CONTACT: For more information, see EPA's Web site: *https://www.epa.gov/eg/dental-effluent-guidelines.* For technical information, contact Ms. Karen Milam, Engineering and Analysis Division (4303T), Office of Water, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone: 202–566–1915; email: *milam.karen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Regulated Entities and Supporting Information

A. Regulated Entities

Entities potentially regulated by this action include:

Category	Example of regulated entity	North American Industry Classification System (NAICS) Code
Industry	A general dentistry practice or large dental facility	621210

This section is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated or affected by this final rule. Other types of entities that do not meet the above criteria could also be regulated. To determine whether your facility would be regulated by this final rule, you should carefully examine the applicability criteria listed in § 441.10 and the definitions in § 441.20 of this final rule and detailed further in Section VI of this preamble. If you still have questions regarding the applicability of this final rule to a particular entity, consult the person listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Supporting Information

This final rule is supported by a number of documents including the Technical and Economic Development Document for the Final Effluent Limitations Guidelines and Standards for the Dental Category (TEDD), Document No. EPA–821–R–16–005. The TEDD and additional records are available in the public record for this final rule and on EPA's Web site at *https://www.epa.gov/eg/dental-effluent-guidelines.*

II. Legal Authority

EPA promulgates this regulation under the authorities of sections 101, 301, 304, 306, 307, 308, and 501 of the CWA, 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342 and 1361 and pursuant to the Pollution Prevention Act of 1990, 42 U.S.C. 13101 *et seq.*

III. Executive Summary

The purpose of this final rule is to set a uniform national standard that will greatly reduce the discharge of mercury-containing dental amalgam to municipal sewage treatment plants, known as POTWs, in the United States. Mercury is a potent neurotoxin that bioaccumulates in fish and shellfish, and mercury pollution is widespread and a global concern that originates from many diverse sources such as air deposition from municipal and industrial incinerators and combustion of fossil fuels. Across the U.S., 12 states and at least 18 localities have established mandatory programs to reduce discharges of mercury to POTWs. As a result of these efforts, along with outreach from the ADA to promote voluntary actions to reduce such discharges, approximately 40 percent of the dentists subject to this rule already have installed amalgam separators. Amalgam separators greatly reduce the discharge of mercury-containing amalgam to POTWs. Amalgam separators are a practical, affordable and readily available technology for capturing mercury at dental offices. The mercury collected by these separators can be recycled. This rule will ensure that mercury discharges to POTWs are effectively controlled at dental offices that discharge wastewater to POTWs.

Many studies have been conducted in an attempt to identify the sources of mercury entering POTWs. According to the 2002 Mercury Source Control and Pollution Prevention Program Evaluation Final Report (DCN DA00006) prepared by the Association of Metropolitan Sewerage Agencies (AMSA), dental offices are the main source of mercury discharges to POTWs. A study funded by the ADA published in 2005 estimated that dental offices contributed 50 percent of mercury entering POTWs (DCN DA00163). Mercury is discharged in the form of waste dental amalgam when dentists remove old amalgam fillings from cavities, and from excess amalgam

waste when a dentist places a new amalgam filling.

While dental offices are not a major contributor of mercury to the environment generally, dental offices are the main source of mercury discharges to POTWs. EPA estimates that across the United States 5.1 tons of mercury and an additional 5.3 tons of other metals found in waste dental amalgam are collectively discharged into POTWs annually. Mercury entering POTWs frequently partitions into the sludge, the solid material that remains after wastewater is treated. Mercury from waste amalgam therefore can make its way into the environment from the POTW through the incineration, landfilling, or land application of sludge or through surface water discharge. Once released into the aquatic environment, certain bacteria can change mercury into methylmercury, a highly toxic form of mercury that bioaccumulates in fish and shellfish. In the U.S., consumption of fish and shellfish is the main source of methylmercury exposure to humans. Removing mercury when it is in a concentrated and easy to manage form in dental amalgam, before it becomes diluted and difficult and costly to remove, is a common sense step to prevent mercury from being released into the environment where it can become a hazard to humans.

The ADA, which supported removal and recycling of mercury from wastewater discharged to POTWs in its comments on the 2014 proposed rule (See DCN EPA–HQ–OW–2014–0693–0434), developed best management practices (BMPs) to facilitate this goal and shared its recommendations widely with the dental community (DCN DA00165). The ADA's voluntary amalgam waste handling and disposal practices include the use of amalgam separators to reduce mercury discharges. In addition, some states and localities have implemented mandatory programs to reduce dental mercury discharges that include the use of amalgam separators.

EPA has concluded that requiring dental offices to remove mercury through relatively low-cost and readily available amalgam separators and BMPs makes sense. Capturing mercury-laden waste where it is created prevents it from being released into the environment. This final rule controls mercury discharges to POTWs by establishing a performance standard for amalgam process wastewater based on the use of amalgam separator technology. The rule also requires dental dischargers to adopt two BMPs, one which prohibits the discharge of waste (''or scrap''), and the other which prohibits the use of line cleaners that may lead to the dissolution of solid mercury when cleaning chair-side traps and vacuum lines.

In addition, the rule minimizes the administrative burden on dental offices subject to the rule, as well as on federal, state, and local regulatory authorities responsible for oversight and enforcement of the new standard. Administrative burden was a concern of many of the commenters on the 2014 proposed rule and EPA has greatly reduced that burden through streamlining the administrative requirements in this final rule.

When EPA establishes categorical pretreatment requirements, it triggers additional oversight and reporting requirements in EPA's General Pretreatment Regulations. The General Pretreatment Regulations specify that Control Authorities (which are often the state or POTW) are responsible for administering and enforcing pretreatment standards, including receiving and reviewing compliance reports. While other industries subject to categorical pretreatment standards typically consist of tens to hundreds of facilities, the dental industry consists of approximately 130,000 offices. Application of the default General Pretreatment Regulation oversight and reporting requirements to such a large number of facilities would be much more challenging. Further, dental office discharges differ from other industries for which EPA has established categorical pretreatment standards. Both the volume of wastewater discharged and the quantity of pollutants in the discharge on a per facility basis are significantly less than other industries for which EPA has established categorical pretreatment standards. Accordingly, this final rule exempts dental offices from the General Pretreatment Regulations' oversight and reporting requirements associated with categorical pretreatment standards, reflecting EPA's recognition that the otherwise-applicable regulatory framework for categorical dischargers would be unlikely to have a significant positive impact on overall compliance with the rule across the dental industry, while imposing a substantial burden on state and local regulating authorities.

In order to simplify implementation and compliance for the dental offices and the regulating authorities, the final rule establishes that dental dischargers are not Significant Industrial Users (SIUs) as defined in 40 CFR part 403, and are not Categorical Industrial Users (CIUs) or ''industrial users subject to categorical pretreatment standards'' as those terms and variations are used in the General Pretreatment Regulations, unless designated such by the Control Authority. While this rule establishes pretreatment standards that require dental offices to reduce dental amalgam discharges, the rule does not require Control Authorities to implement the traditional suite of oversight requirements in the General Pretreatment Regulations that become applicable upon the promulgation of categorical pretreatment standards for an industrial category. This significantly reduces the reporting requirements for dental dischargers that would otherwise apply by instead requiring them to demonstrate compliance with the performance standard and BMPs through a one-time compliance report to their Control Authority. This regulatory approach also eliminates the additional oversight requirements for Control Authorities that are typically associated with SIUs, such as permitting and annual inspections of individual dental offices. It also eliminates additional reporting requirements for the Control Authorities typically associated with CIUs, such as identification of CIUs in their annual pretreatment reports. At the same time, the final rule recognizes the Control Authority's discretionary authority to treat a dental discharger as an SIU and/or CIU if, in the Control Authority's judgement, it is necessary.

EPA estimated the annual costs associated with this rule. EPA's analysis reflects that many dental offices have already taken steps to reduce dental amalgam discharges by discontinuing the use of dental amalgam, adopting the ADA's voluntary best practices, or by meeting existing mandatory state or local requirements. On a national basis, EPA estimates that approximately 40 percent of dental offices subject to this final rule already use amalgam separators (DCN DA00456). Of the remaining 60 percent of dental offices that do not have amalgam separators and that are subject to this final rule, EPA estimates that 20 percent do not place or remove dental amalgam (DCN DA00161). These dentists that do not place or remove dental amalgam—which correspond to 12 percent of the dental offices subject to this final rule—will incur little to no costs as a result of the rule. EPA estimates the remainder (representing 48 percent of the dental offices subject to this final rule) will incur an approximate average annual cost of $800 per office. The total annual cost of this final rule is projected to be $59–$61 million.

This final rule will produce human health and ecological benefits by reducing the estimated annual

nationwide POTW discharge of dental mercury to surface water from 1,003 pounds to 11 pounds. Studies show that decreased point-source discharges of mercury to surface water have resulted in lower methylmercury concentrations in fish, and that such reductions can result in quantifiable economic benefits from improved human health and ecological conditions (DCN DA00148). While not quantified, as noted above, this rule will also reduce mercury releases to the environment associated with the incineration, landfilling, or land application of POTW sludges. Instead, EPA expects all of the collected amalgam will be recycled, rather than released back into the environment.

IV. Background

A. Legal Framework

1. Clean Water Act

Congress passed the Federal Water Pollution Control Act Amendments of 1972, also known as the Clean Water Act (CWA), to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters.'' (33 U.S.C. 1251(a)). The CWA establishes a comprehensive program for protecting our nation's waters. Among its core provisions, the CWA prohibits the discharge of pollutants from a point source to waters of the U.S. except as authorized under the CWA. Under section 402 of the CWA, EPA authorizes discharges by a National Pollutant Discharge Elimination System (NPDES) permit. The CWA establishes a two-pronged approach for these permits: Technology-based controls that establish the floor of performance for all dischargers, and water quality-based limits where the technology-based limits are insufficient for the discharge to meet applicable water quality standards. To serve as the basis for the technology-based controls, the CWA authorizes EPA to establish national technology-based effluent limitations guidelines and new source performance standards for discharges from different categories of point sources, such as industrial, commercial, and public sources, that discharge directly into waters of the U.S.

Direct dischargers (those discharging directly to surface waters) must comply with effluent limitations in NPDES permits. Technology-based effluent limitations in NPDES permits for direct dischargers are derived from effluent limitations guidelines (CWA sections 301 and 304) and new source performance standards (CWA section 306) promulgated by EPA, or based on best professional judgment where EPA has not promulgated an applicable effluent guideline or new source performance standard (CWA section 402(a)(1)(B) and 40 CFR 125.3). The effluent guidelines and new source performance standards established by regulation for categories of industrial dischargers are based on the degree of control that can be achieved using various levels of pollution control technology, as specified in the Act.

EPA promulgates national effluent limitations guidelines and standards of performance for major industrial categories for three classes of pollutants: (1) Conventional pollutants (total suspended solids, oil and grease, biochemical oxygen demand, fecal coliform, and pH) as outlined in CWA section 304(a)(4) and 40 CFR 401.16; (2) toxic pollutants (*e.g.,* toxic metals such as chromium, lead, mercury, nickel, and zinc) as outlined in section 307(a) of the Act, 40 CFR 401.15 and 40 CFR part 423, appendix A; and (3) non-conventional pollutants, which are those pollutants that are not categorized as conventional or toxic (*e.g.,* ammonia-N, formaldehyde, and phosphorus).

The CWA also authorizes EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges from facilities that discharge pollutants indirectly, by sending wastewater to POTWs, as outlined in sections 307(b), (c) and 304(g) of the CWA. EPA establishes national pretreatment standards for those pollutants that may pass through, interfere with, or may otherwise be incompatible with POTW operations. CWA sections 307(b) and (c) and 304(g). The legislative history of the 1977 CWA amendments explains that pretreatment standards are technology-based and analogous to technology-based effluent limitations for direct dischargers for the removal of toxic pollutants. As further explained in the legislative history, the combination of pretreatment and treatment by the POTW is intended to achieve the level of treatment that would be required if the industrial source were making a direct discharge. Conf. Rep. No. 95–830, at 87 (1977), reprinted in U.S. Congress. Senate. Committee on Public Works (1978), A Legislative History of the CWA of 1977, Serial No. 95–14 at 271 (1978). As such, in establishing pretreatment standards, EPA's consideration of pass through for national technology-based categorical pretreatment standards differs from that described in EPA's General Pretreatment regulations at 40 CFR part 403. For categorical pretreatment standards, EPA's approach for pass through satisfies two competing objectives set by Congress: (1) That standards for indirect dischargers be equivalent to standards for direct dischargers; and (2) that the treatment capability and performance of the POTWs be recognized and taken into account in regulating the discharge of pollutants from indirect dischargers. CWA 301(b)(1)(A)(BPT); and 301(b)(1)(E).

2. Effluent Limitations Guidelines and Standards

EPA develops Effluent Guidelines Limitations and Standards (ELGs) that are technology-based regulations for specific categories of dischargers. EPA bases these regulations on the performance of control and treatment technologies. The legislative history of CWA section 304(b), which is the heart of the effluent guidelines program, describes the need to press toward higher levels of control through research and development of new processes, modifications, replacement of obsolete plants and processes, and other improvements in technology, taking into account the cost of controls. Congress has also stated that EPA need not consider water quality impacts on individual water bodies as the guidelines are developed; see Statement of Senator Muskie (October 4, 1972), reprinted in U.S. Senate Committee on Public Works, Legislative History of the Water Pollution Control Act Amendments of 1972, Serial No. 93–1, at 170).

There are standards applicable to direct dischargers (dischargers to surface waters) and standards applicable to indirect dischargers (dischargers to POTWs). The types of standards relevant to this rulemaking are summarized here.

a. Best Available Technology Economically Achievable (BAT)

BAT represents the second level of stringency for controlling direct discharge of toxic and nonconventional pollutants. In general, BAT-based effluent guidelines and new source performance standards represent the best available economically achievable performance of facilities in the industrial subcategory or category. Following the statutory language, EPA considers the technological availability and the economic achievability in determining what level of control represents BAT. CWA section 301(b)(2)(A). Other statutory factors that EPA considers in assessing BAT are the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, and non- water quality environmental impacts, including energy requirements and such other factors as the

Administrator deems appropriate. CWA section 304(b)(2)(B). The Agency retains considerable discretion in assigning the weight to be accorded these factors. *Weyerhaeuser Co.* v. *Costle,* 590 F.2d 1011, 1045 (D.C. Cir. 1978).

b. Best Available Demonstrated Control Technology (BADCT)/New Source Performance Standards (NSPS)

NSPS reflect effluent reductions that are achievable based on the best available demonstrated control technology (BADCT). Owners of new facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the most stringent controls attainable through the application of the BADCT for all pollutants (that is, conventional, nonconventional, and toxic pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements. CWA section 306(b)(1)(B).

c. Pretreatment Standards for Existing Sources (PSES)

Pretreatment standards apply to dischargers of pollutants to POTWs; Pretreatment Standards for Existing Sources are designed to prevent the discharge of pollutants to POTWs that pass through, interfere with, or are otherwise incompatible with the operation of POTWs, including sludge disposal methods of POTWs. Categorical pretreatment standards for existing sources are technology-based and are analogous to BAT effluent limitations guidelines, and thus the Agency typically considers the same factors in promulgating PSES as it considers in promulgating BAT. See *Natural Resources Defense Council* v. *EPA,* 790 F.2d 289, 292 (3rd Cir. 1986).

d. Pretreatment Standards for New Sources (PSNS)

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. New indirect discharges have the opportunity to incorporate into their facilities the best available demonstrated technologies. In establishing pretreatment standards for new sources, the Agency typically considers the same factors in promulgating PSNS as it considers in promulgating NSPS (BADCT).

e. Best Management Practices (BMPs)

Section 304(e) of the CWA authorizes the Administrator to publish regulations, in addition to effluent limitations guidelines and standards for certain toxic or hazardous pollutants, ''to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage which the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment process . . . and may contribute significant amounts of such pollutants to navigable waters.'' In addition, section 304(g), read in concert with section 501(a), authorizes EPA to prescribe as wide a range of pretreatment requirements as the Administrator deems appropriate in order to control and prevent the discharge into navigable waters, either directly or through POTWs, any pollutant which interferes with, passes through, or otherwise is incompatible with such treatment works. (see also *Citizens Coal Council* v. *U.S. EPA,* 447 F3d 879, 895–96 (6th Cir. 2006) (upholding EPA's use of non-numeric effluent limitations and standards); *Waterkeeper Alliance, Inc.* v. *U.S. EPA,* 399 F.3d 486, 496–97, 502 (2d Cir. 2005) (EPA use of non-numerical effluent limitations in the form of BMPs are effluent limitations under the CWA); and *Natural Res. Def. Council, Inc.* v. *EPA,* 673 F.2d 400, 403 (D.C. Cir. 1982) (''section 502(11) [of the CWA] defines 'effluent limitation' as 'any restriction' on the amounts of pollutants discharged, not just a numerical restriction.''))

B. Dental Category Effluent Guidelines Rulemaking History and Summary of Public Comments

EPA published the proposed rule on October 22, 2014, and took public comment through February 20, 2015. During the public comment period, EPA received approximately 200 comments. EPA also held a public hearing on November 10, 2014. Administrative burden was a concern of many of the commenters on the 2014 proposed rule, particularly from regulatory authorities responsible for oversight and enforcement of the new standard. Commenters also provided additional information on amalgam separators (*e.g.,* costs, models, and design) as well as information on some other approaches to reduce pollutant discharges from dentists. Commenters also offered ways to improve and/or clarify the proposed pretreatment standards, including the proposed numerical efficiency and operation and maintenance requirements. See DCN DA00516 for these comments and EPA's responses.

C. Existing State and Local Program Requirements

Currently, 12 states (Connecticut, Louisiana,[1] Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington) have mandatory programs to reduce dental mercury discharges. Additionally, at least 18 localities (located in California, Colorado, Ohio, and Wisconsin) similarly have mandatory dental amalgam reduction pretreatment programs. EPA analyzed readily available information about these programs and found commonalities (DCN DA00524). For example, all require the use of amalgam separators and most specify associated operating and maintenance requirements. The majority of these programs also require some type of best management practices, and at least a one-time compliance report to the regulating authority.

D. Roles and Responsibilities Under the National Pretreatment Program

The National Pretreatment Program requires industrial dischargers that discharge to POTWs to comply with pretreatment standards. The General Pretreatment Regulations in 40 CFR part 403 establish roles and responsibilities for entities involved in the implementation of pretreatment standards. This section summarizes the roles and responsibilities of Industrial Users (IUs), Control Authorities, and Approval Authorities. For a detailed description, see the preamble for the proposed rule (79 FR 63279–63280; October 22, 2014).

An IU is a nondomestic source of indirect discharge into a POTW, and in this rule is the dental discharger. The Control Authority may be the POTW, the state, or EPA, depending on whether the POTW or the state is approved by EPA to administer the pretreatment program. The Control Authority is the POTW in cases where the POTW has an approved pretreatment program. The Control Authority is the state, where the POTW has not been approved to administer the pretreatment program, but the state has been approved. The Control Authority is EPA where neither the POTW nor the state have been approved to administer the pretreatment program. The Approval Authority is the

[1] Louisiana state requirements do not explicitly require dental offices to install amalgam separators; dental offices must follow BMPs recommended by the ADA in 1999. ADA added amalgam separators to the list of BMPs in 2008.

State (Director) in an NPDES authorized state with an approved pretreatment program; or the EPA regional administrator in a non-NPDES authorized state or NPDES state without an approved state pretreatment program.

Typically, an IU is responsible for demonstrating compliance with pretreatment standards by performing self-monitoring, submitting reports and notifications to its Control Authority, and maintaining records of activities associated with its discharge to the POTW. The Control Authority is the regulating authority responsible for implementing and enforcing pretreatment standards. The General Pretreatment Regulations require certain minimum oversight of IUs by Control Authorities. The required minimum oversight includes receipt and analysis of reports and notifications submitted by IUs, random sampling and analyzing effluent from IUs, and conducting surveillance activities to identify occasional and continuing non-compliance with pretreatment standards. The Control Authority is also responsible for taking enforcement action as necessary. For IUs that are designated as Significant Industrial Users (SIUs), Control Authorities must inspect and sample the SIU effluent annually, review the need for a slug control plan, and issue a permit or equivalent control mechanism. IUs subject to categorical pretreatment standards are referred to as Categorical Industrial Users (CIUs). The General Pretreatment Regulations define SIU to include CIUs. The Approval Authority is responsible for ensuring that POTWs comply with all applicable pretreatment program requirements. Among other things, the Approval Authority receives annual pretreatment reports from the Control Authority. These reports must identify which IUs are CIUs.

E. Minamata Convention on Mercury

On November 6, 2013, the United States joined the Minamata Convention on Mercury, a new multilateral environmental agreement that addresses specific human activities that are contributing to widespread mercury pollution. The agreement identifies dental amalgam as a mercury-added product for which certain measures should be taken. Specifically, the Convention lists nine measures for phasing down the use of mercury in dental amalgam, including promoting the use of best environmental practices in dental offices to reduce releases of mercury and mercury compounds to water and land. Nations that are parties to the Convention are required to implement at least two of the nine measures to address dental amalgam. This final rule contributes to the U.S.'s efforts to meet the measures called for in the treaty.

V. Description of Dental Industry & Dental Amalgam Wastewater Sources and Management

A. Dental Industry

The industry category affected by this final rule is Offices of Dentists (NAICS 621210), which comprises establishments of health practitioners primarily engaged in the independent practice of general or specialized dentistry, or dental surgery. These practitioners operate individual or group practices in their own offices or in the offices of others, such as hospitals or health maintenance organization medical centers. They can provide either comprehensive preventive, cosmetic, or emergency care, or specialize in a single field of dentistry.

According to the 2012 Economic Census, there are 133,221 U.S. dental offices owned or operated by 125,275 dental firms.[2] Only 2 percent of all dental firms are multi-unit, the rest are single-unit. The growth of the number of dental offices remained steady over the past decade with an average increase of 1 percent per year.

The industry includes mostly small businesses with an estimated over 99 percent of all offices falling below the Small Business Administration (SBA) size standard ($7.5 million in annual revenue). Using Census Bureau data, EPA estimates an average revenue for offices at $787,190 per year with an average of 6.6 employees per establishment.

According to ADA data, approximately 80 percent of the dental industry engages in general dentistry. Approximately 20 percent are specialty dentists such as periodontists, orthodontists, radiologists, maxillofacial surgeons, endodontists, or prosthodontists (DCN DA00460).

Dentistry may also be performed at larger institutional dental offices (military clinics and dental schools). Since EPA does not know if these offices are included in the 2012 Economic Census data, EPA conservatively assumed the largest offices are not present in the data, and so added an estimate of 415 larger institutional dental offices across the nation. For the final rule, EPA updated this number based on comments received on the proposed rule.

[2] A firm is a business organization, such as a sole proprietorship, partnership, or corporation.

B. Dental Amalgam Wastewater Sources and Management

Dental amalgam consists of approximately 49 percent mercury by weight. Mercury is the only metal that is in its liquid phase at room temperature, and it bonds well with powdered alloy. This contributes to its durability in dental amalgam. The other half of dental amalgam is usually composed of 35 percent silver, 9 percent tin, 6 percent copper, 1 percent zinc and small amounts of indium and palladium (DCN DA00131).

Sources of dental amalgam discharges generally occur in the course of two categories of activities. The first category of discharges may occur in the course of treating a patient, such as during the placement or removal of a filling. When filling a cavity, dentists overfill the tooth cavity so that the filling can be carved to the proper shape. The excess amalgam is typically rinsed into a cuspidor, or suctioned out of the patient's mouth. In addition to filling new cavities, dentists also remove old restorations that are worn or damaged. Removed restorations also may be rinsed into a cuspidor or suctioned out of the patient's mouth. Based on information in the record (DCN DA00456), removed restorations is the largest contributor of mercury in dental discharges.

The second category of dental amalgam discharges occurs in the course of activities not directly involved with the placement or removal of dental amalgam. Preparation of dental amalgam, disposing of excess amalgam, and flushing vacuum lines with corrosive chemicals present opportunities for dental amalgam to be discharged.

The use of dental amalgam has decreased steadily since the late 1970s as alternative materials such as composite resins and glass ionomers have become more widely available. Estimates show that placements of dental amalgam have decreased on average by about 2 to 3% per year (74 FR 38686; August 4, 2009). Based on this information, EPA estimates that mercury in dental amalgam discharges to POTWs will decrease by about half within the next 25 years. While the use of dental amalgam continues to decline, EPA estimates that approximately 2 tons of mercury would continue to be discharged to POTWs in 2040.

The typical plumbing configuration in a dental office consists of a chair-side trap for each chair, and a central vacuum pump with a vacuum pump filter. Chair-side traps and vacuum pump filters remove approximately 78

percent of dental amalgam particles from the wastewater stream (DCN DA00163). EPA identified three major technologies that capture dental amalgam waste, in addition to chair-side traps and vacuum pump filters, before it is discharged to the POTW: Separators, ion exchange, and wastewater containment systems. EPA also identified BMPs that have a significant impact on dental amalgam discharges.

1. Amalgam Separators

An amalgam separator is a device designed to remove solids from dental office wastewater. Amalgam separators remove amalgam particles from the wastewater through centrifugation, sedimentation, filtration, or a combination of any of these methods. Practically all amalgam separators on the market today rely on sedimentation because of its effectiveness and operational simplicity.

The vast majority of amalgam separators on the market today have been evaluated for their ability to meet the current American National Standards Institute's (ANSI) Standard for Amalgam Separators (ANSI/ADA Standard No. 108 for Amalgam Separators). This standard incorporates the International Organization for Standardization (ISO) Standard for Dental Amalgam Separators (*http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42288*).[3] The current ISO standard for amalgam separators is ISO 11143. ISO established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam solids using specified test procedures in a laboratory setting. In order to meet the ISO standard, a separator must achieve 95 percent removal or greater of total solids. The ISO standard also includes certain design requirements and requirements for instructions for proper use and maintenance. For example, for non-sedimentation amalgam separators, the ISO 11143 standard requires a warning system such as an auditory or visual sign to indicate when the separator's efficiency is compromised to ensure that the operator is aware that the separator is not operating optimally. For sedimentation separators, the requirement can be met by providing instructions that would allow the operator to ascertain the operating status of the amalgam separator.

Based on reported removal efficiencies of a range of amalgam separators currently on the market that meet the ISO standard, separators obtain a median of 99 percent removal efficiency (see Chapter 7 of the TEDD) of total dental solids. When existing chair-side traps and vacuum pump filters are used upstream of the amalgam separators, the combined treatment system can achieve total mercury removal rates exceeding 99 percent (DCN DA00008).

Solids collected by the amalgam separator may be a combination of dental amalgam, biological material from patients, and any other solid material sent down the vacuum line. The collected solids must be handled in accordance with federal, state and local requirements. EPA regulates the disposal of mercury-containing hazardous waste under the Resource Conservation and Recovery Act (RCRA). A mercury-containing waste can be considered hazardous in two ways: (1) As a listed hazardous waste; or (2) as a characteristic hazardous waste. Unused elemental mercury being discarded would be a listed hazardous waste (waste code U151). Persons who generate hazardous waste, such as a waste that exhibits the hazardous characteristics for mercury, are subject to specific requirements for the proper management and disposal of that waste. The federal RCRA regulatory requirements differ depending upon how much hazardous waste a site generates per month. Most dental practices generate less than 100 kilograms of non-acute hazardous waste per month and less than 1 kilogram of acute hazardous waste per month. Such facilities are therefore classified as ''Very Small Quantity Generators'' (VSQGs). VSQGs are not subject to most of the RCRA hazardous waste requirements.

Many states have additional requirements for the handling of mercury, including waste dental amalgam. Chapter 6 of the TEDD provides additional details on the handling requirements for states that require dentists to control dental mercury dischargers. To facilitate compliance with state and local requirements, several amalgam separator manufacturers offer services that facilitate the transport of waste amalgam to facilities that separate mercury from other metals in dental amalgam and recycle the mercury, keeping it out of the environment. EPA recommends that dental dischargers take advantage of such services. In 2012, ADA posted a directory of amalgam recyclers on its Web site. See DCN DA00468.

For more information about amalgam separators, see the proposed rule (79 FR 63265; October 22, 2014).

2. Polishing To Remove Dissolved Mercury From Wastewater

Mercury from dental amalgam in wastewater is present in both the particulate and dissolved form. The vast majority (≤99.6 percent) is particulate (DCN DA00018). An additional process sometimes referred to as ''polishing'' uses ion exchange to remove dissolved mercury from wastewater. Dissolved mercury has a tendency to bind with other chemicals, resulting in a charged complex. Ion exchange is the process that separates these charged amalgam particles from the wastewater. For ion exchange to be most effective, the incoming wastewater must first be treated to remove solids. Then the wastewater needs to be oxidized (creating a charge on the amalgam particles) in order for the resin or mercury capturing material to capture the dissolved mercury. Therefore, ion exchange will not be effective without first being preceded by a solids collector and an oxidation process. The data available to EPA indicate that total additional mercury reductions with the addition of polishing are typically about 0.5 percent (DCN DA00164). This is not surprising since, as indicated above, dissolved mercury contributes such a small portion to the total amount of mercury in wastewater. In addition to polishing as described above, EPA is aware that vendors are developing amalgam separators with an improved resin for removing dissolved mercury. For additional discussion on polishing, see proposal (79 FR 63266; October 22, 2014).

3. Wastewater Retention Tanks

Commenters on the proposed rule identified wastewater retaining tanks as a third technology to reduce mercury discharges from dental offices to POTWs. Where currently used, these systems collect and retain *all*[4] amalgam process wastewater. The wastewater remains in the wastewater retention tank until it is pumped out of the tank and transferred to a privately owned wastewater treatment facility. This eliminates the discharge of amalgam process wastewater and the associated

[3] ANSI is the coordinator of the U.S. voluntary consensus standards system. An ISO document may be nationally adopted as an ANS as written or with modifications to its content that reflect technical deviations to the ISO standard that have been agreed upon through a consensus process. In other words, a consensus of U.S. experts, in an open and due process based environment, agreed that ISO 11143 with U.S. modifications is appropriate for adoption as an ANS.

[4] Dental offices using wastewater retention tanks must ensure that all amalgam process wastewater is collected by the wastewater retention tanks. Any uncollected amalgam process wastewater that is discharged to the POTW is subject to this rule.

pollutants from a dental office to a POTW.

4. Best Management Practices

In addition to technologies, EPA also identified best management practices currently used in this industry (and included in the ADA BMPs) to reduce dental amalgam discharges. In particular, EPA identified two BMPs to control dental amalgam discharges that would not be captured by an amalgam separator and/or polishing unit. Oxidizing line cleaners can solubilize bound mercury. If oxidizing cleaners are used to clean dental unit water lines, chair side traps, or vacuum lines that lead to an amalgam separator, the line cleaners may solubilize any mercury that the separator has captured, resulting in increased mercury discharges. One BMP ensures the efficiency of amalgam separators by prohibiting use of oxidizing line cleaners including but not limited to, bleach, chlorine, iodine and peroxide, that have a pH lower than 6 or greater than 8.[5]

Flushing waste amalgam from chair-side traps, screens, vacuum pump filters, dental tools, or collection devices into drains also presents additional opportunities for mercury to be discharged from the dental office. The second BMP prohibits flushing waste dental amalgam into any drain.

VI. Final Rule

A. Scope and General Applicability

Consistent with the proposal, dental offices that discharge to POTWs are within the scope of this final pretreatment rule.[6] EPA solicited information in the proposal from the public on its preliminary finding that, with few exceptions, dental offices do not discharge wastewater directly to surface waters. EPA did not receive any comments containing data to contradict this finding. Therefore, EPA is not establishing any requirements for direct wastewater discharges from dental offices to surface waters at this time.

The final rule applies to wastewater discharges to POTWs from offices where the practice of dentistry is performed, including large institutions such as dental schools and clinics; permanent or temporary offices, home offices, and facilities; and including dental offices owned and operated by federal, state, or local governments including military bases. The final rule does not apply to wastewater discharges from dental offices where the practice of dentistry consists exclusively of one or more of the following dental specialties: Oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics. As described in the TEDD, these specialty practices are not expected to engage in the practice of amalgam restorations or removals, and are not expected to have any wastewater discharges containing dental amalgam.

The final rule also does not apply to wastewater discharges to POTWs from mobile units. EPA proposed to apply the standards to mobile units (typically a specialized mobile self- contained van, trailer, or equipment from which dentists provide services at multiple locations), soliciting comments and data pertaining to them (79 FR 63261; October 22, 2014). However, EPA is not establishing requirements for mobile units at this time because it has insufficient data to do so. EPA does not have, nor did commenters provide, data on the number, size, operation, or financial characteristics of mobile units. EPA also has minimal information on wastewater discharges from mobile units, and/or practices employed to minimize dental amalgam in such discharges. Therefore, any further evaluation of requirements for mobile units is not possible at this time, and the final rule requirements do not apply to mobile units.

B. Existing Source (PSES) Option Selection

After considering all of the relevant factors and dental amalgam management approaches discussed in this preamble and TEDD, as well as public comments, EPA decided to establish PSES based on proper operation and maintenance of one or more ISO 11143[7] compliant amalgam separators and two BMPs—a prohibition on the discharge of waste (or ''scrap'') amalgam to POTWs and a prohibition on the use of line cleaners that are oxidizing or acidic and that have a pH higher than 8 or lower than 6. EPA finds that the technology basis is ''available'' as that term is used in the CWA because it is readily available and feasible for all dental offices subject to this rule. Data in the record demonstrate that the technology basis is extremely effective in reducing pollutant discharges in dental wastewater to POTWs as the median efficacy of ISO compliant amalgam separators on the market in the U.S. is 99.3 percent. Moreover, ADA recommends that dentists use the technology on which this rule is based (ISO compliant amalgam separators and BMPs). Further, as described in Section III, EPA estimates that approximately 40 percent of dental offices potentially subject to this rule currently use amalgam separators on a voluntary basis or are in states or localities with laws requiring the use of amalgam separators. Many dentists have used amalgam separators and BMPs for at least a decade. For those dental offices that have not yet installed an amalgam separator, EPA estimates this is a low-cost technology with an approximate average annual cost of $800[8] per office. EPA's economic analysis shows that this rule is economically achievable (see Section IX). Finally, EPA also examined the incremental non-water-quality environmental impacts of the final pretreatment standards and found them to be acceptable. See Section XII.

EPA did not establish PSES based on technologies that remove dissolved mercury such as polishing. EPA is not aware of any state or local regulations that require ion exchange or that require removal of dissolved mercury. Commenters raised operational concerns with ion exchange citing a pilot study for the department of Navy. EPA also lacks adequate performance data to assess the efficacy of polishing for nationwide use. While even very small amounts of mercury have environmental effects, EPA lacks sufficient data to conclude that there is a significant difference in the performance between traditional amalgam separators and polishing. Moreover, current information suggests that polishing is not available for nationwide use because the typical dental office may not have adequate space to install the treatment train needed for effective polishing and because there are few polishing systems on the market today in comparison to traditional amalgam separators. Lastly, EPA estimates that the capital costs of the polishing system, as a stand-alone system, are approximately four times that of the amalgam separator even though the costs for chemical use, regenerating the resin, filter replacement, and other operational costs were not reported (DCN DA00122). These factors led EPA to find that polishing is not ''available'' as that term is used in the CWA.

[5] Many alternatives use enzymatic or other processes that do not lead to the dissolution of mercury when used to clean chairside traps, and vacuum lines. See DCN DA00215.

[6] The final rule does not apply to dental discharges to septic systems.

[7] ISO 11143 Standard as incorporated and updated by ANSI Standard 108 (ANSI 108/ISO 11143 Standard).

[8] This estimate is based on the average annualized cost for dental offices that do not currently have an amalgam separator. See DCN DA00458.

EPA also did not establish PSES based on wastewater retention tanks. Capital costs for wastewater retention tanks are approximately twice that of the amalgam separator (DCN DA00461). EPA does not have information on the costs incurred by the dental office to send the collected wastewater off-site to a privately owned treatment facility (may also be referred to as a centralized waste treatment facility or CWT). Furthermore, wastewater retention tanks require space, and EPA determined that the typical dental office may not have adequate space to install the tanks. In addition, EPA is only aware of one vendor currently offering this technology and service combination (vendor transfers the collected wastewater to a privately owned treatment facility), and the vendor's service area is limited to a few states. Therefore, EPA did not find this technology to be available to the industry as a whole.

C. New Source (PSNS) Option Selection

After considering all of the relevant factors and technology options discussed in this preamble and in the TEDD, as well as public comments, EPA decided to establish PSNS based on the same technologies identified above as PSES. As previously noted, under section 307(c) of the CWA, new sources of pollutants into POTWs must comply with standards that reflect the greatest degree of effluent reduction achievable through application of the best available demonstrated control technologies. Congress envisioned that new treatment systems could meet tighter controls than existing sources because of the opportunity to incorporate the most efficient processes and treatment systems into the facility design. The technologies used to control pollutants at existing offices, amalgam separators and BMPs, are fully available to new offices. In addition, data from EPA's record show that the incremental cost of an amalgam separator compared to the cost of opening a new dental office is negligible; therefore, EPA determined that the final PSNS present no barrier to entry (see Section IX below). Similarly, because EPA projects that the incremental non-water quality environmental impacts associated with controls for new sources would not exceed those for existing sources, EPA concludes the non-water quality environmental impacts are acceptable. Therefore, this final rule establishes PSNS that are the same as those for PSES.

EPA rejected other technologies as the basis for PSNS for the same reasons the Agency rejected other technology bases for PSES.

D. Requirements

1. Performance Standard

EPA finalized the performance standards based on the same technology identified in the proposed rule, amalgam separators.

EPA proposed a standard that would require dental dischargers to remove a specified percentage of total mercury from amalgam process wastewater and to follow the BMPs. Recognizing the impracticality of collecting and analyzing wastewater samples to demonstrate compliance with the standard for this industry, EPA included a provision by which dental offices could demonstrate compliance by certifying they were following the required BMPs and using an amalgam separator that achieved the specified percentage when tested for conformance with the ISO standard. EPA received comments regarding the proposed requirement. Commenters questioned the specified percent reduction, and raised concerns that the proposed standard could require dental offices to measure the percent removal being achieved by their amalgam separator, which was not the Agency's intent. In response to these comments, the final rule specifies a performance standard—BMPs and the use of an amalgam separator(s) compliant with the ISO standard rather than specifying a numerical reduction requirement. The final rule also includes a provision such that the performance standard can be met with the use of an amalgam removing technology other than an amalgam separator (equivalent device). EPA included this provision to incorporate future technologies that achieve comparable removals of pollutants from dental discharges as amalgam separators but that may not fall under the amalgam separator classification. Because the rule does not include a numerical limit, the performance standards also specify certain operation and maintenance requirements for the amalgam separator or comparable device to ensure they are operated optimally.

The final rule allows dental offices to continue to operate existing amalgam separators for their lifetime or ten years (whichever comes first), as long as the dental discharger complies with the other rule requirements including the specified BMPs, operation and maintenance, reporting, and recordkeeping requirements. Once the separator needs to be replaced or the ten-year period has ended, dental offices will need to replace the amalgam separator with one that meets the requirements of the final rule. EPA does not want to penalize existing dental offices or institutional dental offices that have already installed amalgam separators voluntarily or to comply with state or local requirements. EPA recognizes that these offices may currently have amalgam separators in place that do not meet the ANSI ADA specification or the criteria of the ISO 11143 2008 standard. EPA did not want to establish a rule that would require dental offices with existing separators that still have a remaining useful life to be retrofitted with new separators, both because of the additional costs incurred by dental offices that adopted technology to reduce mercury discharges ahead of EPA's requirements and because of the additional solid waste that would be generated by disposal of the existing separators.

In addition to installing one or more amalgam separators compliant with the ISO 11143 standard (or its equivalent) and implementing the required BMPs, the pretreatment standards specify certain operating and maintenance requirements for the amalgam separator. For example, the final rule requires a documented amalgam separator inspection to ensure the separator is performing properly. As explained in Section V, malfunctioning separators or separators that have reached their capacity are ineffective. Therefore, in order to ensure that mercury is not discharged from the facility, it is important that dentists know the operational status of their amalgam separator (see 40 CFR 441.40(c)). As such, the final rule requires the separator to be inspected per the manufacturer's instructions. In addition, as explained in Section V, the ISO standard specifies non-sedimentation separators must have a visual or auditory warning indicator when the separator is nearly full or operating in by-pass mode. While not required for sedimentation amalgam separators, some manufacturers of sedimentation amalgam separators include visual or auditory warning indicators. Because warning indicators make it easy to detect when the separator is not operating optimally, EPA encourages dental offices to select an amalgam separator with a warning indicator when installing a new amalgam separator.

EPA is aware that some amalgam separator vendors (in addition to providing the needed equipment) or service providers offer service contracts to maintain the system. These vendors also typically provide waste

management services for the collected solids. Some vendors also provide the necessary documentation and reports required by existing state and local programs. EPA encourages but does not require dental offices to consider such services, as they may aid compliance with the rule.

2. Applicability to Dental Offices That Do Not Place or Remove Dental Amalgam

In the final rule, dental dischargers that do not place dental amalgam, and do not remove dental amalgam except in limited emergency or unplanned, unanticipated circumstances are exempt from any further requirements as long as they certify such in their One-time Compliance Report to their Control Authority. In this way, if, over time, the use of dental amalgam is phased out as a restorative material, the requirements of this rule will no longer apply. By limited circumstances, EPA means, dental offices that remove amalgam at a frequency less than five percent of its procedures. As described below, based on the record, on average, this percent approximates to 9 removals per office per year (DCN DA00467).

Dental amalgam traditionally has been used as a restorative material for cavities because the malleability of newly mixed amalgam makes it easy to place into cavities and because of its durability over time. While still used in many dental offices in the U.S., some dental offices have elected not to use dental amalgam and instead use only non-mercury based filling materials, such as composite resins and glass ionomer cements (DCN DA00495). As explained in Section IV, removed restorations are the largest contributor of mercury in dental discharges. Some dental offices have also elected not to remove amalgam restorations.

EPA recognizes some dental offices only remove dental amalgam extremely infrequently, where there is an unplanned, unanticipated procedure. At the same time, for accepting new patients during the normal course of business, EPA would expect offices to inquire as to whether the patient has mercury fillings and not accept patients that have such fillings unless they install a separator or equivalent treatment in accordance with this rule. EPA proposed that dental offices that certify that they do not place or remove amalgam except in limited emergency circumstances would be exempt from any further requirements of the rule. EPA is clarifying in the final rule that the limited circumstances provision applies to the removal, but not to the placement of dental amalgam. A dental office that stocks amalgam capsules clearly intends to place amalgam, and does not represent the type of limited circumstance this provision is intended to address. Commenters largely supported this approach, and most commenters suggested EPA define limited emergency circumstances. The frequency recommended by these commenters ranged from once a quarter to 96 times a year (DCN DA00467).

EPA is including the limited circumstances provision in the final rule to allow a dental office that does not reasonably expect to place or remove dental amalgam to provide immediate treatment, such as where unplanned, unanticipated removal of the amalgam is necessary at that facility at that time, in the professional judgment of the dentist. EPA's intent is to exclude dental offices from the rule's requirements, other than a one-time report, for unplanned removals. In EPA's view, dental offices that remove amalgam at a frequency more often than five percent of its procedures are not likely engaging in only limited, unplanned removals. EPA estimates that on average, a single chair dental office would remove amalgam 183 times per year (DCN DA00467). An amalgam removal rate that represents less than five percent of this frequency consists of approximately nine removals per year, on average, respectively. However, because EPA does not have, nor did commenters provide, data on the frequency of such unplanned and unanticipated instances nationwide, the final rule does not include a specific definition of limited circumstances. Rather, EPA expects a dental office to carefully consider its operation in light of the information provided above and only certify accordingly to their Control Authority if it meets the situation EPA described.

3. Dental Discharger Reporting and On-Site Paperwork Compliance Requirements

Dental dischargers subject to this rule must comply with a one-time reporting requirement specified in the final rule in lieu of the otherwise applicable reporting requirements in 40 CFR part 403. Submission of reports as specified in this rule satisfies the reporting requirements in 40 CFR parts 403 and 441. For dental offices that do not place or remove dental amalgam except in limited circumstances, dental offices must submit a One-Time Compliance Report that includes information on the facility and a certification statement that the dental discharger does not place dental amalgam and does not remove amalgam except in limited circumstances. For dental offices that place or remove dental amalgam, the One-Time Compliance Report must include information on the dental facility and its operations and a certification that the dental discharger meets the requirements of the applicable performance standard. Dentists that utilize a third party to maintain their separator must report that information in their One-Time Compliance Report. Dentists that do not utilize a third party to maintain the amalgam separator(s) must provide a description of the practices employed by the office to ensure proper operation and maintenance. EPA suggests dental offices consider use of signs displayed prominently in the office or electronic calendar alerts to remind staff of dates to perform and document monthly inspections, cartridge replacement, etc.

If a dental practice changes ownership (which is a change in the responsible party, as defined in 40 CFR 403.12(l)), the new owner must submit a One-Time Compliance Report that contains the required information.

The One-Time Compliance Report must be signed by (1) a responsible corporate officer if the dental office is a corporation; (2) a general partner or proprietor if the dental office is a partnership or sole proprietorship; or (3) a duly authorized representative of the responsible corporate officer, or general partner or proprietor. This does not preclude a third party from submitting the report on behalf of a dental office as long as the submission also includes a proper signature as described above.

The final rule does not require electronic reporting nor does it prevent electronic reporting. EPA received several comments requesting that EPA develop an electronic compliance reporting system as a part of this final rule. These commenters generally advocated for electronic reporting due to the size of the industry and the proposed annual reporting requirement. During development of the final rule, EPA considered several variations of requirements for dental dischargers to report electronically (which would have necessitated an electronic system). Most commonly, electronic systems are preferable when reports must be submitted on a periodic basis. EPA ultimately decided not to specify electronic reporting in the final rule after it determined the final rule would only require a one-time compliance report from each affected dental discharger.

Still, EPA recognizes that some Control Authorities may prefer to receive the one-time reports electronically or to provide affected

dental dischargers with the option to report electronically. EPA also recognizes that electronic submittal of required reports could increase the usefulness of the reports, is in keeping with current trends in compliance reporting, and could result in less burden on the regulated community and the Control Authorities. EPA may develop and make available, via its E-Enterprise portal, an electronic reporting system that Control Authorities could use to facilitate the receipt of reports from dental dischargers, if they choose to do so. At some future date, EPA could decide to revise this final rule to require electronic reporting. If it chose to do so, EPA would first propose the revisions and provide an opportunity for public review and comment.

Finally, the final rule requires dental offices to document certain operation and maintenance requirements and maintain all records of compliance, as described in the regulation, and to make them available for inspection.

4. Control Authority Oversight/ Reporting

EPA proposed to amend selected parts of the General Pretreatment Regulations (40 CFR part 403) in order to simplify oversight requirements for the approximately 117,000 dental offices subject to the proposed rule. Specifically, EPA proposed to amend 40 CFR part 403 to create a new classification of categorical industrial users specifically tailored to pretreatment standards for dental offices, dental industrial user (DIU). EPA proposed that as long as a dental office complied with the requirements for DIUs, that it would not be considered an SIU. Among other things, this would have reduced the General Pretreatment Regulation oversight requirements for Control Authorities, such as the requirement to issue a control mechanism and annual inspection and sampling.

EPA received numerous comments related to the proposed change, particularly from the Control Authorities. These commenters largely supported the reduced oversight requirements in the proposal, but encouraged EPA to reduce them further so that dental offices would never be SIUs, primarily due to concerns over the associated burden given the large number of dental offices potentially subject to the rule. In addition, Control Authorities raised concerns that they would have to update state and local laws to take advantage of the proposed changes to part 403 that would reduce the oversight requirements. They also raised concerns about additional reporting requirements for the Control Authorities typically associated with CIUs, such as identifying CIUs in their annual pretreatment report to the Approval Authority.

In response, EPA did not revise the General Pretreatment Standards to create the proposed DIU category and associated requirements. Rather, this rule establishes for the purposes of part 441, that dental dischargers are not SIUs or CIUs as defined in 40 CFR part 403 unless designated as such by the Control Authority. This regulatory structure achieves the same goal as the proposed revisions to the General Pretreatment Standards—simplification of oversight requirements—without creating a need for updates to state and local laws. By establishing that dental dischargers are not SIUs or CIUs in the final rule, EPA eliminates the application of specific oversight and reporting requirements in 40 CFR part 403 such as permitting and annual inspections of dental dischargers for SIUs and CIUs unless the Control Authority chooses to apply these requirements to dental offices. This means that Control Authorities have discretion under the final rule to determine the appropriate manner of oversight, compliance assistance, and enforcement.[9] Further, the final rule reduced reporting for dental offices (and associated oversight requirements by Control Authorities) in comparison to reporting requirements for other industries subject to categorical pretreatment standards, as it requires only a One-Time Compliance Report be submitted to the Control Authority. The One-Time Compliance Report requirements specific to dental dischargers are included in this rule rather than in the General Pretreatment regulations so that they may be implemented directly. In summary, for this final rule, the Control Authorities must receive the One-Time Compliance Reports from dental dischargers and retain that notification according to the standard records retention protocol contained in § 403.12(o).

Where EPA is the Control Authority, EPA expects to explore compliance monitoring approaches that support sector-wide compliance evaluations, to the extent practicable. States and POTWs that are the Control Authority may elect to use the same approach but are not required to do so. One approach may be periodic review and evaluation of nationwide data on releases of dental amalgam metals (*e.g.,* mercury), relying on Discharge Monitoring Reports from POTWs, Annual Biosolids Reports from POTWs, emissions data from sludge incinerators, and supplemental data submitted to EPA under the Toxic Releases Inventory program. EPA may utilize an approach to compliance inspections that focuses on a statistically valid sample of the regulated community. EPA may then use the inspection findings from such an approach to identify common areas of noncompliance, which would inform decisions about needed outreach, compliance assistance, and training materials. EPA will work with state and local Control Authorities, the ADA and other partners to tailor oversight and outreach to the issues where such oversight and outreach is most likely to achieve compliance across the dental sector.

5. Interaction With Existing State and Local Mandatory Dental Amalgam Reduction Programs

The final rule applies to both dental offices that are subject to existing mandatory state or local dental amalgam reduction programs and those that are not. Some proposal commenters, many of whom are in states and localities with existing programs, questioned the application of this rule to dentists already subject to state and local programs noting the duplicative requirements. While EPA found that many of the existing programs contained at least one attribute of this final rule (*e.g.* separators, reporting, BMPs, operation and maintenance), the majority did not contain all of the attributes. Generally, the additional requirements (and associated costs) of this final rule are incremental over existing mandatory state or local dental amalgam reduction requirements. For example, a dentist located in a state or locality that does not require one or both of the BMPs specified in this rule must implement both BMPs. While the requirements of this rule are incremental to existing state and local regulatory requirements, EPA finds they are necessary to achieve the intended environmental objectives of the rule. Applying categorical pretreatment standards to pollutant discharges from dental offices irrespective of existing discharge requirements is consistent with the general approach to pretreatment standards under the CWA in that it establishes uniform requirements that form the floor of performance for all dischargers in a regulated category.

In addition, requiring all dental offices to meet the same requirements, regardless of the applicability of other

[9] Nothing stated in this section shall be construed so as to limit EPA's inspection and enforcement authority.

state or local requirements, avoids substantial implementation challenges and potential confusion associated with alternative approaches. EPA considered several approaches for accommodating dentists in states and localities with existing and local requirements. For example, EPA considered exempting dentists subject to equivalent state and local requirements from the scope of this rule. EPA rejected this approach, in part, due to the complexities and potential confusion associated with evaluating and communicating the equivalency of state and local requirements to this rule, particularly as they may change over time.

The rule establishes clear requirements for all parties and compliance with the final rule is simple and straightforward for dental offices and the regulating authorities. It requires dental offices to install and operate a separator, to implement two BMPs, and to submit a One-time Compliance Report to the Control Authority. Thereafter, the dental office will be required to conduct ongoing operation and maintenance and maintain associated records. These activities can be facilitated by third parties such as dental office suppliers and amalgam separator manufacturers. EPA does not expect the federal requirements to conflict with existing state or local mandatory amalgam reduction requirements. Rather, EPA concludes this final rule imposes only incremental additional requirements (*e.g.,* one-time compliance report) to their Control Authority, if any, on dental offices already subject to state or local amalgam reduction requirements. For Control Authorities, because EPA significantly reduced the oversight requirements associated with this rule, the incremental costs and burden to apply the final rule's requirements to dental facilities subject to some existing mandatory dental amalgam reduction requirements are minimal. The only incremental requirement associated with this rule is for the Control Authority to receive, review, and retain a One-time Compliance Report from dentists subject to this rule.

6. Variances

The provision of this rule establishing that dental dischargers are not SIUs or CIUs unless designated as such by the Control Authority does not change the otherwise applicable variances and modifications provided by the statute. For example, EPA can develop pretreatment standards different from the otherwise applicable requirements for an individual existing discharger subject to categorical pretreatment standards if it is fundamentally different with respect to factors considered in establishing the standards applicable to the individual discharger. Such a modification is known as a ''fundamentally different factors'' (FDF) variance. See 40 CFR 403.13 and the preamble to the proposed rule (79 FR 63278–63279, October 22, 2014). FDF variances traditionally have been available to industrial users subject to categorical pretreatment standards. Whether or not a dental discharger is an SIU or CIU, it is subject to categorical pretreatment standards and therefore eligible to apply for an FDF variance.

E. Pollutants of Concern and Pass Through Analysis

CWA section 301(b) directs EPA to eliminate the discharge of all pollutants where it is technologically available and economically achievable (after a consideration of the factors specified in section 304(b) of the Act). The first step in such an analysis is typically to identify Pollutants of Concern (POCs)—or the pollutants potentially regulated in the effluent guideline. For this rule, EPA identifies the primary metals in dental amalgam as pollutants of concern: Mercury, silver, tin, copper, and zinc.

Generally, in determining whether pollutants pass through a POTW when considering the establishment of categorical pretreatment standards, EPA compares the median percentage of the pollutant removed by POTWs achieving secondary treatment with the median percentage of the pollutant removed by facilities meeting BAT effluent limitations. EPA deems a pollutant to pass through a POTW when the percentage removed by POTWs is less than the percentage removed by direct dischargers complying with BPT/BAT effluent limitations. In this manner, EPA can ensure that the combined treatment at indirect discharging facilities and POTWs is at least equivalent to that obtained through treatment by a direct discharger, while also considering the treatment capability of the POTW. In the case of this final rulemaking, where EPA is only developing pretreatment standards, EPA compares the POTW removals with removals achieved by indirect dischargers using the technology that otherwise satisfies the BAT factors.

Historically, EPA's primary source of POTW removal data is its 1982 ''Fate of Priority Pollutants in Publicly Owned Treatment Works'' (also known as the 50 POTW Study). This well documented study presents data on the performance of 50 POTWs achieving secondary treatment in removing toxic pollutants. As part of the development of ELGs for the Centralized Waste Treatment (CWT) Industry promulgated in December 2000, EPA developed and documented a methodology, including data editing criteria, to calculate POTW percent removals for various toxic pollutants from the data collected in the study. EPA provided the opportunity for public comment on the percent removal methodology and the resulting percent removals in the CWT proposal. EPA similarly used and presented this methodology and data in subsequent ELG proposals and final rules. Using its long-standing approach, for this final rule, EPA determined the median percent removal by POTWs achieving secondary treatment is 90.2 percent for total mercury, and 42.6 percent to 88.3 percent for the other pollutants of concern.

As described above, the 50 POTW Study measured pollutant reductions on the basis of total metals. Total metals include particulate (suspended) and dissolved (soluble) forms of the metal. As discussed above, while mercury is present in dental amalgam in both the particulate and dissolved form, the vast majority (>99.6 percent) is particulate. While EPA does not have information on the distribution of the other metals, EPA reasonably assumes the same distribution for the other metals. Because secondary treatment technologies are not designed to remove dissolved metals, EPA assumes dissolved metals are not removed by POTWs and that the percent reductions for POTWs represent particulate reductions.

To determine the median percent removal of the pollutants of concern by amalgam separators, EPA collected information on the efficacy of existing separators. EPA excluded those separators that did not meet the 2008 ISO standards. At proposal, EPA determined the median percent removal of total mercury to be 99.0 percent, which is the reported removal when testing each of the amalgam separators marketed in the U.S. as conforming to the ISO standard (DCN DA00233). Commenters noted that existing data on the effectiveness of separators is measured as a percent reduction in mass, reflecting the dental amalgam particulates (rather than total mercury) collected by the device. EPA agrees the ISO standard evaluates particulates from dental amalgam rather than total mercury, and has adjusted its terminology accordingly. Based on updated information in the record, EPA determined the median percent removal of particulates by amalgam separators that meet the 2008 ISO standards is 99.3 percent. As such, because the median

percent removal of amalgam separators exceeds the median percent removal of well-operated POTWs employing secondary treatment for mercury and the other POCs, EPA determines that mercury and the other POCs pass through.

In addition to comments relating to dissolved mercury, EPA received other comments and data pertaining to the proposed median percent removal of ISO compliant amalgam separators. Some commenters supported the percentage identified in the proposal, noting that certain states require the same level of performance, or identifying separators documented as achieving or exceeding that removal efficiency. Other commenters questioned EPA's use of the data collected when laboratories certify amalgam separators to meet the ISO standard. More specifically, they asserted that the 2008 ISO standard requires the removal efficiency of the amalgam separator to be at least 95 percent on a mass fraction basis and as such, the ISO standard is not a validated test for measuring higher efficiencies. These commenters offered no data to demonstrate that the reported removals in excess of 95 percent were inaccurate, nor did commenters provide other efficiency data for amalgam separators. As it represents the best data available for the final rule, EPA appropriately used the data as reported to estimate the efficacy of amalgam separators for these purposes. EPA notes that even if commenters correctly characterized the minimum percent removal efficiency of amalgam separators meeting the 2008 ISO standard as 95 percent, this is a higher removal rate than the median percent removal by POTWs for all POCs. Therefore, while EPA based its analysis in the final rule on the percent removals as reported, under either case, EPA determines that mercury and the other POCs pass through.

Other commenters stated the 50 POTW Study data were old, and that current POTW removals are higher than 90 percent. Some provided case studies, many of which reflected POTWs with advanced treatment capabilities rather than secondary treatment. In particular, the National Association of Clean Water Agencies (NACWA) submitted data from a nationwide voluntary survey of its members regarding mercury reductions at POTWs. Based on its analysis of the data collected in this survey, NACWA calculated a three-year average removal efficiency of 94 percent.[10] EPA notes that even if EPA were to accept these data and analyses as presented by NACWA without further review, it would confirm EPA's conclusion that pass through of POCs occurs because this percentage is less than the median efficiency of 2008 ISO compliant amalgam separators of 99.3 percent.

EPA, however, gave full consideration to the NACWA survey and subjected the mercury influent and effluent data from the 41 POTWs from that survey to similar review and data editing criteria as influent and effluent data collected for the 50 POTW Study. In this way, EPA attempted to give the NACWA data full and equal consideration as the historical data from the 50 POTW Study. EPA created a database of the raw data in order to conduct its analysis. (DCN DA00463). When EPA calculated the median percent removal of the non-edited raw data as submitted by NACWA, the median plant performance was 93.8 percent, with a range of 57.2 percent to 99.1 percent. In reviewing the data used in that calculation, EPA identified numerous data points that would not satisfy the data editing criteria applied in the 50 POTW Study, including data points representing combined data rather than raw data, order of magnitude outlier concentrations, and incorrectly reported units of measure. Other discrepancies between data and analyses from the 50 POTW Study and NACWA survey include upward bias of using data from voluntary respondents, representing non-detect influent concentrations as zero,[11] inclusion of several POTWs using BNR (biological nutrient removal) and other advanced treatment expected to perform better than secondary treatment, overrepresentation of areas with existing dental amalgam reduction programs, and underrepresentation of certain geographical areas. Sensitivity analyses around these data are found in the record. (DCN DA00464).

Consequently, for all of the reasons identified above, for this final rule, EPA finds that data from the 50 POTW Study continues to represent the best data available to determine the percent removed nationwide by well operated POTWs employing secondary treatment. Based on the information in its record including full consideration of comments, EPA appropriately concludes that the median percent removal of amalgam separators is higher than the median percent removal of POTWs for mercury and the other pollutants of concern. As such, EPA concludes mercury and the other POCs pass through.

VII. Technology Costs

This section summarizes EPA's approach for estimating incremental compliance costs to implement changes associated with this rule, while the TEDD provides detailed information on the methodology. The costing methodology for the final rule is the same as that described in the proposal (79 FR 63269; October 22, 2014); however, EPA updated some of the specific data elements. EPA estimated compliance costs using data collected through EPA's Health Services Industry Detailed Study (August 2008) [EPA–821–R–08–014], a review of the literature, information supplied by vendors, and data submitted with comments on the proposed rule. In estimating the total cost of the regulatory options, EPA estimated costs for the following components: Capital costs and other one-time costs; installation costs; annual operation and maintenance costs; and recordkeeping and reporting costs. EPA incorporated information received in comments pertaining to specific elements of the cost analysis, resulting in an increase in the initial installation cost and a minor increase in the average costs of dental amalgam separators that meet the 2008 ISO standard. In addition, EPA adjusted the reporting and recordkeeping costs to reflect the final rule requirements.

The cost estimates reflect the incremental costs attributed only to this final rule. For example, offices required by a state or local program to have an amalgam separator compliant with the 2008 ISO 11143 standard will not incur costs to retrofit a separator as a result of this rule. Others may certify that they do not place or remove amalgam. Such offices may still have costs under this final rule such as those associated with the one-time reporting requirement to certify that they do not place or remove amalgam. EPA's cost methodology assumes dental offices would use the required BMPs in combination with 2008 ISO 11143 amalgam separators to comply with the rule. All final cost estimates are expressed in terms of 2016 dollars.

EPA used a model office approach to calculate costs of this rule. Under this approach, EPA developed a series of model dental offices that exhibited the

[10] EPA notes that in conducting its pass through analysis, EPA calculates and compares median percent removals rather than average percent removals.

[11] EPA generally handles non-detect values in the reported data by replacing them with a value of one-half of the detection level for the observation that yielded the non-detect. This methodology is standard procedure for the ELG program as well as Clean Water Act assessment and permitting, Safe Drinking Water Act monitoring, and Resource Conservation and Recovery Act and Superfund programs; and this approach is consistent with previous ELGs.

typical characteristics of the regulated dental offices, and then calculated costs for each type of model office. EPA then determined how many of each model office accurately represented the full universe of affected offices. While this part of the methodology remains unchanged from the proposal, EPA updated the number of offices in each model to reflect current existing state and local programs and, in the case of very large offices, to reflect new data obtained in public comments on the number of clinics and schools subject to this rule.

A. Costs for Model Dental Offices

EPA used the model approach to estimate costs for offices that place or remove amalgam for this final rule. EPA developed compliance costs for seven models, where each model is based on the number of chairs in an office. The ranges for each model are as follows: 1 to 2 chairs, 3 chairs, 4 chairs, 5 chairs, 6 chairs, 7–14 chairs (average of 10 chairs), and 15 chairs. EPA developed the 15 chairs model specifically to represent large institutional offices. This is discussed separately below in Section VII.B. EPA developed two sets of costs for each model: One for offices that do not use an amalgam separator and one for offices that do use an amalgam separator.

For those offices that currently do not use an amalgam separator, EPA estimated one-time and annual costs. One-time costs include purchase of the separator and installation, and preparation of the One-time Compliance Report. Annual costs, for those offices that do use an amalgam separator, include visual inspection, replacement of the amalgam-retaining unit (*e.g.,* cartridge or filter), separator maintenance and repair, recycling (preparation and services), and recordkeeping. Recordkeeping costs include documentation of inspection, separator maintenance and repair, and recycling (preparation and services). EPA also estimated periodic recordkeeping costs associated with repairs and One-Time Compliance Reports for new offices, which are included in the total of recordkeeping costs. Annual costs also include a cost offset, reflecting a cost savings as a result of changes that occur in the dental office due to the final rule requirements. More specifically, EPA received data in comments that an amalgam separator would protect the vacuum system filter and impeller blade from small particles, resulting in less frequent replacement and servicing of these elements when an amalgam separator has been installed. In the final rule cost analysis, EPA accordingly reduced the overall operation and maintenance costs for those dental offices that do not already have an amalgam separator. This cost offset reflects the reduced cost to dental offices of servicing the vacuum system filter and impeller blade. A summary of costs for dental offices that do not currently use amalgam separators may be found in Tables VII–1 and VII–2, see the TEDD for more details.

TABLE VII–1—SUMMARY OF ONE TIME MODEL FACILITY COSTS ($2016) FOR DENTAL OFFICES THAT DO NOT CURRENTLY USE AMALGAM SEPARATORS

Cost element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5 [12]	6	7 to 14	15
Separator Purchase	$437	$697	$1,058	$1,291	$2,424
Installation	235	276	276	358	942
One-Time Compliance Report	23	23	23	23	23

TABLE VII–2—SUMMARY OF ANNUAL MODEL FACILITY COSTS ($2016) FOR DENTAL OFFICES THAT DO NOT CURRENTLY USE AMALGAM SEPARATORS

Cost element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5 [13]	6	7 to 14	15
Replacement Parts	$275	$386	$559	$732	$1,078
Separator Maintenance	115	115	115	115	115
Maintenance Cost Off-set	−75	−75	−75	−75	−75
Recycling	91	91	91	91	91
Visual Inspection	18	18	18	18	18
Recordkeeping	62	62	62	62	62

For those offices that already have an amalgam separator, EPA calculated costs for certain incremental annual costs associated with the amalgam separator required for this rule. Because these offices have separators, EPA only included a one-time cost for a One-Time Compliance Report ($23/office). Annual costs for such offices include visual inspection, replacement of the amalgam-retaining unit, separator maintenance and repair, recycling (preparation and services), and recordkeeping. Because these offices have amalgam separators in place, they are already incurring the majority of these costs irrespective of this final rule. As such, for those components (*e.g.,* replacement of the cartridge and operation and maintenance), EPA calculated their incremental costs as a portion (percentage) of annual costs for dental offices without technology in place. Recordkeeping costs include documentation of inspection, separator maintenance and repair, and recycling (preparation and services). EPA also estimated periodic recordkeeping costs associated with repairs and One-Time Compliance Reports for new offices, which are included in the total of recordkeeping costs. EPA did not include the cost offset in this model, as

[12] EPA assumed the separator can be sized for 3, 4, or 5 chairs, but has kept these three model office sizes distinct because the economic analysis evaluates different revenues for each of these sized offices.

[13] EPA assumed the separator can be sized for 3, 4, or 5 chairs, but has kept these three model office sizes distinct because the economic analysis evaluates different revenues for each of these sized offices.

described above. A summary of these annual costs may be found in Table VII–3, see the TEDD for more details.

TABLE VII–3—SUMMARY OF ANNUAL MODEL FACILITY COSTS ($2016) FOR DENTAL OFFICES THAT CURRENTLY USE AMALGAM SEPARATORS

Cost element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5 [14]	6	7 to 14	15
Replacement Parts	$138	$193	$280	$366	$539
Separator Maintenance	58	58	58	58	58
Recycling	45	45	45	45	45
Inspection	18	18	18	18	18
Recordkeeping	62	62	62	62	62

In assessing the long term costs of rule compliance for these model offices (those with and without existing separators), EPA assumed that amalgam separators would have a service life of 10 years, at which time the amalgam separators would need to be replaced (DCN DA00163). Furthermore, the cost model assumes all dental amalgam separators installed prior to this rule would need to be replaced within 10 years of the effective date of this rule. Therefore, for the purposes of estimating compliance costs, EPA assumed that all offices subject to this rule would incur the cost of installing a new amalgam separator 10 years after the effective date of this rule. However, because various modifications needed by the office for initial amalgam separator installation would have already been completed, EPA has projected the installation costs for amalgam separators would be one-half of the cost of the original installation. EPA assumed that all dental offices would continue to incur recurring expenses such as O&M beyond year 10 in the same way as described for the initial installation. To the extent dental offices either close or certify they no longer remove or place amalgam, the costs are likely overstated.

EPA projects that there will be no incremental costs associated with the required BMPs because (1) costs for non-oxidizing, pH neutral line cleaners are roughly equivalent to other line cleaners; and (2) dental offices will not incur additional costs by changing the location for flushing waste amalgam.

B. Costs for Larger Institutional Dental Offices

Institutional dental offices (*e.g.,* military clinics or dental schools) have a larger number of chairs than the typical dental office. For these institutional dental offices, EPA developed a costing methodology based on the methodology for offices described above. For purposes of costs, consistent with the proposal, EPA assumed the average institutional office has 15 chairs.[15] As shown in Chapter 9 of the TEDD, EPA has cost information for five amalgam separators that have a maximum design ranging from 17–22 chairs. EPA also has costs for a unit that can be custom sized for chair sizes of 16 or greater. EPA used the information for these six separators to estimate costs for institutional facilities. See DCN DA00454. These costs are likely overstated as they do not reflect opportunities the largest offices may have to share costs,[16] and they do not assume any economies of scale. In addition, it is possible that the largest offices have multiple plumbing lines, allowing the installation of dental amalgam separators (or equivalent devices) only for those chairs used for placing or removing amalgam. See the proposed preamble and the TEDD for additional details on the costing methodology for institutional offices.

VIII. Pollutant Loads

As was the case for costing, EPA does not have office-specific discharge data for the approximately 117,000 dental offices potentially subject to this rule. Instead, EPA modeled the baseline, pre-rule discharges of mercury based on nationwide estimates of amalgam restorations and removals, and did not calculate the pollutant reductions on a per office basis. Rather, EPA calculated average mercury loadings by dividing the total number of annual procedures by the total number of dentists performing the procedure.[17] The technology basis used to estimate the compliance costs of this rule includes 2008 ISO 11143 amalgam separators available on the market today, and certain BMPs. The median performance of these separators is 99.3 percent. EPA assumes all offices have chair-side traps or a combination of chair-side traps and vacuum filters that result in 68 percent and 78 percent collection of dental amalgam, respectively (DCN DA00163). After accounting for mercury reductions achieved through existing chair-side traps and vacuum pump filters, EPA's analysis reduces remaining mercury loads to reflect the combination of chair-side traps, vacuum filters, and amalgam separators. Therefore, EPA assumed a post-rule reduction in mercury loads to POTWs based on a 99.8 percent removal rate. This is the same approach and data that EPA presented in the proposal (79 FR 623275; October 22, 2014).

Amalgam is comprised of roughly 49 percent mercury, 35 percent silver, 9 percent tin, 6 percent copper and 1 percent zinc (DCN DA00131). As explained earlier in Section VI, EPA concludes that the technology basis would be equally effective in reducing discharges of silver, tin, copper, and zinc as it is in reducing mercury. EPA therefore applied the same approach to estimating reductions of other metals found in dental amalgam. In other words, EPA assumes chair-side traps and the combination of chair-side traps and vacuum filters will result in 68 percent and 78 percent collection of these metals, respectively. Remaining amalgam metals are further reduced by an amalgam separator, as discussed above.

[14] EPA assumed the separator can be sized for 3, 4, or 5 chairs, but has kept these three model office sizes distinct because the economic analysis evaluates different revenues for each of these sized offices.

[15] This represents the number of chairs that can be used for the placement and/or removal of amalgam at a particular location. EPA received comments for institutional facilities indicating they had 7, 15, or 25 chairs. EPA selected the median of these values for purposes of this analysis.

[16] For example, multiple offices located in a single building or complex may be able to share plumbing, vacuum systems, and may be able to install a larger separator rather than each office having its own separator.

[17] Because this approach is based on the number of dentists, it includes those dentists both at offices and institutional offices.

A. National Estimate of Annual Pollutant Reductions to POTWs Associated With This Rule [18]

1. Mercury

EPA estimates the approximately 55,000 offices that install separators would obtain 99.3 percent removal of particulate mercury through the use of amalgam separators (median removal efficiency of amalgam separators; see Chapter 7 of the TEDD). This would result in reduction of particulate mercury discharges to POTWs by approximately 5.1 tons. Amalgam separators are not effective in removing dissolved mercury. However, dissolved mercury accounts for much less than 1 percent of the total mercury, so the form of mercury removed from discharges to POTWs is assumed to consist of particulate (solids) only.

2. Other Metals

As explained earlier in Section VI, EPA concludes that the technology basis for this final rule would be equally effective in reducing discharges of silver, tin, copper, and zinc as it is in reducing mercury. Accordingly, EPA estimates a reduction of these metal discharges to POTWs of approximately 5.3 tons.

3. Total Reductions

EPA estimates this final rule would annually reduce particulate mercury and other metal particulate discharges by a total of 10.3 tons.

B. National Estimate of Annual Pollutant Reductions to Surface Waters Associated With This Rule

In order to evaluate final discharges of mercury (and other metals) to waters of the U.S. by the POTW, EPA used its 50 POTW Study to calculate POTW removals of each metal. As explained above, at baseline and prior to implementation of this rule, EPA estimates 5.1 tons of dental mercury particulates are collectively discharged annually to POTWs. Based on the 50 POTW Study, EPA estimates POTWs remove 90.2 percent of dental mercury from the wastewater. Thus, POTWs collectively discharge 1,003 pounds of mercury from dental amalgam to surface waters annually. Under this final rule, 99.8 percent of mercury particulates currently discharged annually to POTWs will be removed prior to the POTW. The POTWs then further remove 90.2 percent of the remaining particulate mercury from the wastewater. This reduces the total amount of dental mercury particulates discharged from POTWs nationwide to surface water to 11 pounds of mercury annually. In other words, discharges of dental mercury to waters of the U.S. from POTWs are expected to be reduced by 992 pounds per year.[19] Similarly, EPA's 50 POTW Study data shows 42.6 percent to 88.3 percent of other metals in the wastewater are removed by POTWs. As explained above, EPA estimates 5.3 tons of other metals are also collectively discharged annually from dental offices to POTWs. Thus, POTWs collectively discharge approximately 2,178 pounds of other dental metals to surface waters annually. Following compliance with this rule, the total amount of other dental metal discharges from POTWs nationwide to surface waters will be approximately 24 pounds or a reduction of 2,153. See Chapter 11 of the TEDD for more details.

IX. Economic Impact Analysis

This section summarizes EPA's assessment of the total annual costs and impacts of the final pretreatment standards on the regulated industry.

A. Social Cost Estimates

As described earlier in Section VI of this preamble, EPA based the technology standard for the final rule on a widely available technology, amalgam separators, and employment of readily available BMPs. Section VII provides a detailed explanation of how EPA estimated compliance costs for model dental offices. As applicable, EPA annualized the capital costs over a 20-year period at a discount rate of 7 percent and 3 percent [20] and summed these costs with the O&M and reporting/recordkeeping costs to determine an annual compliance cost estimate for each model facility. See the TEDD for more details.

In order to develop a national estimate of social costs [21] based on these model offices, EPA estimated the number of dental offices represented by each model office. EPA categorized dental offices based on the number of chairs in each office.[22] The 2012 Economic Census does not provide information on the distribution of dental offices by the number of chairs in each office. However, two studies, the ADA National Study and a Colorado Study, estimate distribution of dentist offices by number of chairs (DCN DA00141 and DCN DA00149). EPA used these two data sources to correlate the number of chairs per office to the revenue range of dental offices. EPA averaged the correlation of these two studies to estimate the number of dental offices by the number of chairs. The results are reported in table IX–1:

TABLE IX–1—NUMBER OF DENTAL OFFICES BY NUMBER OF CHAIRS

Number of chairs	Number of offices by chair size		
	ADA survey	Colorado survey	Average
1–2 chairs	16,606	12,976	14,791
3 chairs	57,841	33,738	31,329
4 chairs	.....	38,928	33,924
5 chairs	35,638	19,032	18,425
6 chairs	.....	7,786	12,802
7+ chairs	23,136	20,762	21,949

[18] EPA's approach is not dynamic, as it does not account for declining use of dental amalgam. See additional discussion in V.B.

[19] Dissolved mercury accounts for a portion of surface water discharges, because amalgam separators do not remove dissolved mercury.

[20] See the TEDD for the reported analyses using both a 7 percent and 3 percent discount rate.

[21] Costs of the rule, from the standpoint of cost to society, include compliance costs and administrative costs to Control Authorities. Social costs would also incorporate any adjustment based on a quantity demand response to a change in price driven by a price change due to cost pass-through to consumers. For this analysis, EPA is not able to demonstrate an observable change in price for dental services, therefore no observable change in amount of visits (quantity demanded). Therefore, EPA makes no adjustment to social costs based on a change in quantity.

[22] Amalgam separators are typically designed based on the number of chairs.

TABLE IX–1—NUMBER OF DENTAL OFFICES BY NUMBER OF CHAIRS—Continued

Number of chairs	Number of offices by chair size		
	ADA survey	Colorado survey	Average
Total	133,221	133,221	133,221

To estimate nationwide social costs, EPA multiplied the estimated total annualized costs of rule compliance for each model office by the estimated number of dental offices represented by that model (*i.e.* with the indicated number of chairs and with/without existing amalgam separators). In EPA's analysis, for dental offices that do not place or remove amalgam, EPA assigned them costs for a baseline-compliance report. EPA then summed the values for each chair range over the number of chair ranges to yield the total estimated compliance cost. Similarly, EPA calculated costs for institutional offices by multiplying the compliance cost for its model institutional offices (15-chair model) by the number of estimated institutional offices indicated in Section V. Lastly, EPA estimated costs for Control Authorities to administer the final rule. Details of this cost analysis can be found in the TEDD. See Table IX–2 for EPA's estimate of total nationwide annualized social costs for this final rule using a 3 percent discount rate.[23]

TABLE IX–2—TOTAL ANNUALIZED SOCIAL COSTS BY NUMBER OF CHAIRS

[Millions of 2016 dollars]

Number of chairs	Total annualized costs by chair size [1]	
	Colorado survey	ADA survey
1–2 chairs	$4.2	$5.4
3 chairs	13.6	23.3
4 chairs	15.7	.....
5 chairs	7.7	16.4
6 chairs	4.0	.....
7–14 chairs	13.1	14.6
15 chairs	0.3	0.3
Cost to Control Authorities	0.8	0.8
Total Annualized Social Costs	59.4	60.8

[1] These costs reflect estimated costs discounted to the year of promulgation. EPA assumed that initial capital outlays and initial incurrence of ongoing compliance expenses would occur in the third year following rule promulgation. EPA assumed that the amalgam separator technology would have a service life of 10 years, and used a 20-year analysis period to allow for one-time replacement of capital equipment 10 years following the initial installation. A 3 percent discount rate was used for the analysis reported in this table; see the TEDD for the analysis reported with a 7% discount rate.

B. Economic Impact

EPA devised a set of tests for analyzing economic achievability. As is often EPA's practice, the Agency conducted a cost-to-revenue analysis to examine the relationship between the costs of the rule to current (or pre-rule) dental office revenues as a screening analysis. In addition, EPA chose to examine the financial impacts of the rule using two measures that utilize the data EPA has on dental office baseline assets and estimated replacement capital costs: (1) Ratio of the Final Rule's Capital Costs to Total Dental Office Capital Assets and (2) Ratio of the Final Rule's Capital Costs to Annual Dental Office Capital Replacement Costs.

EPA did not conduct a traditional closure analysis for this final rule because EPA does not have detailed data on baseline financial conditions of dental offices. Also, closure analyses typically rely on accounting measures such as present value of after-tax cash flow, and such accounting measures are difficult to implement for businesses that are organized as sole proprietorships or partnerships, as typically is the case in the dental industry. EPA considered whether it should exclude these offices from the analyses, which is described further in EPA's proposal (79 FR 63272; October 22, 2014). Because EPA did not receive any comments to the contrary, EPA used the same assumptions for this final rule as it did at proposal with regard to low-revenue offices. EPA concluded that offices making less than $25,400 were baseline closures as traditionally accounted for in cost and economic impact analysis for effluent guidelines rulemakings. Using the Economic Census, EPA estimated that to be approximately 531 offices. Still, because of the uncertainty here, EPA analyzed the impacts twice: (1) Excluding dental offices that could represent baseline closures and (2) including all offices in the analysis. For each of the three analyses conducted below, EPA used the same methodology for the final rule's impact analysis as described in the proposal because EPA did not receive any comments to suggest a different approach for each impact analysis. Lastly, EPA used a 7 percent discount rate for the costs used in these three analyses described below. See the proposed rule for further description of the analyses below (79 FR 63272; October 22, 2014).

[23] As a point of clarification, social costs equal the sum of compliance costs and administrative costs. Also, EPA used a 3 percent discount rate for the social costs analysis.

1. Cost-to-Revenue Analysis

To provide an assessment of the impact of the rule on dental offices, EPA used a cost-to-revenue analysis as is standard practice when looking at impacts to small businesses under the Regulatory Flexibility Act (RFA) to determine if a rule has the potential to have a significant impact on a substantial number of small entities. The cost-to-revenue analysis compares the total annualized compliance cost of each regulatory option with the revenue of the entities.

EPA estimated the occurrence of annualized compliance costs exceeding the 1 percent and 3 percent of revenue thresholds for the final rule twice: (1) Excluding dental offices that could represent baseline closures (excluding baseline set-aside offices), and (2) including all offices in the analysis (including baseline set-aside offices).

Table IX–3 summarizes the results from this analysis. As shown there, under either scenario, over 99 percent of dental offices subject to this rule would incur annualized compliance costs of less than 1 percent of revenue. With baseline set-asides excluded from the analysis, 808 offices (0.7 percent of offices using dental amalgam and exceeding the set-aside revenue threshold) are estimated to incur costs exceeding 1 percent of revenue; no offices are estimated to incur costs exceeding 3 percent of revenue. With baseline set-asides included in the analysis, 1,217 offices (1 percent of offices using dental amalgam) are estimated to incur costs exceeding 1 percent of revenue; 174 offices (0.1 percent of offices using dental amalgam) are estimated to incur costs exceeding 3 percent of revenue.

TABLE IX–3—COST-TO-REVENUE ANALYSIS IMPACT SUMMARY

Number of chairs	Total offices by chair size	Costs >1% revenue		Costs >3% revenue	
		Number	Percent	Number	Percent
Excluding Baseline Set-Aside Offices from Analysis					
1–2 chairs	12,914	808	6.3	0	0.0
3 chairs	27,353	0	0.0	0	0.0
4 chairs	29,619	0	0.0	0	0.0
5 chairs	16,087	0	0.0	0	0.0
6 chairs	11,177	0	0.0	0	0.0
7–14 chairs	19,163	0	0.0	0	0.0
Total	116,313	808	0.7	0	0.0
Including Baseline Set-Aside Offices in Analysis					
1–2 chairs	12,914	1,217	9.4	174	1.4
3 chairs	27,353	0	0.0	0	0.0
4 chairs	29,619	0	0.0	0	0.0
5 chairs	16,087	0	0.0	0	0.0
6 chairs	11,177	0	0.0	0	0.0
7–14 chairs	19,163	0	0.0	0	0.0
Total	116,313	1,217	1.0	174	0.1

2. Ratio of the Rule's Capital Costs to Total Dental Office Capital Assets

This ratio examines the initial spending on capital costs of compliance in relation to the baseline value of assets on the balance sheet of dental office businesses. EPA assumes a low ratio implies limited impact on dental offices' ability to finance the initial spending on capital costs of the final rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting.

Table IX–4 reports the findings from this analysis, specifically the weighted average of the initial spending on the proposed rule's capital costs divided by total assets of dental office across the revenue range/number-of-chairs analysis combinations. With baseline set-asides excluded from the analysis, the resulting initial capital costs to total capital assets values are low, with an average value 0.4 percent to 0.7 percent for the no technology in-place case and zero percent for the technology in-place case. With baseline closures included in the analysis, the resulting initial capital costs to total capital assets values are low, with an average value 0.4 percent to 0.7 percent for the no technology in-place case and 0 percent for the technology in-place case.

TABLE IX–4—INITIAL SPENDING AS PERCENTAGE OF PRE-RULE TOTAL DENTAL OFFICE CAPITAL ASSETS[1]

Number of chairs	Technology in place		No technology in place	
	Low	High	Low	High
Excluding Baseline Set-Aside Offices from Analysis				
1–2 chairs	0.1	0.0	2.4	1.2
3 chairs	0.0	0.0	0.9	0.5
4 chairs	0.0	0.0	0.6	0.4
5 chairs	0.0	0.0	0.3	0.2
6 chairs	0.0	0.0	0.3	0.2
7–14 chairs	0.0	0.0	0.2	0.1

TABLE IX–4—INITIAL SPENDING AS PERCENTAGE OF PRE-RULE TOTAL DENTAL OFFICE CAPITAL ASSETS[1]—Continued

Number of chairs	Technology in place		No technology in place	
	Low	High	Low	High
Weighted Average	0.0	0.0	0.7	0.4
Including Baseline Set-Aside Offices in Analysis				
1–2 chairs	0.1	0.0	3.0	1.5
3 chairs	0.0	0.0	0.9	0.5
4 chairs	0.0	0.0	0.6	0.4
5 chairs	0.0	0.0	0.3	0.2
6 chairs	0.0	0.0	0.3	0.2
7–14 chairs	0.0	0.0	0.2	0.1
Weighted Average	0.0	0.0	0.7	0.4

[1] EPA used the baseline asset value for the minimum (reported as low) and maximum (reported as high) revenue values by number-of-chairs category as the denominator for the ratio. Total final rule compliance costs, as described in Section IX above, were assigned to each number-of-chairs category as the numerator for the ratio.

3. Comparison of the Rule's Capital Costs to Annual Dental Office Capital Replacement Costs

EPA also compared the initial spending on capital costs of compliance associated with this rule to the estimated capital replacement costs for a dental office business (*e.g.,* computer systems, chairs, x-ray machines, etc.) across all chair sizes. The capital replacement costs represent a value that dental offices may reasonably expect to spend in any year to replace and/or upgrade dental office capital equipment. EPA assumes a low ratio implies limited impact on dental offices' ability to finance the initial spending on capital costs of the final rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting. As expected, the results for this ratio are higher than the previous ratio in the test above, given that EPA expects replacement costs would be smaller than total capital assets. EPA performed this test because this ratio is based on a different data source, and so it provides an independent check that abstracts from the limitations of the data used in the test above. The resulting values for the final rule range from 2.0 percent to 2.8 percent, with a weighted average of 2.4 percent across all chair size ranges.

TABLE IX–5—INITIAL SPENDING AS PERCENTAGE OF ESTIMATED ANNUAL DENTAL OFFICE CAPITAL REPLACEMENT COSTS [1]

Number of chairs	Percent
1–2 chairs	2.7
3 chairs	2.8
4 chairs	2.3
5 chairs	2.0
6 chairs	2.3
7 chairs	2.5
8 chairs	2.3
9 chairs	2.1
Weighted Average	2.4

[1] EPA estimated capital replacement costs, accounting for the total value of equipment purchases for different numbers of chairs, and the composition of purchases by equipment life category by number-of-chairs as the denominator for the ratio. EPA assigned total final rule compliance costs, as described above in Section IX, to each number-of-chairs as the numerator for the ratio.

C. Economic Achievability

The analyses performed above inform the potential economic impact of this final rule on the dental office sector. In the cost-to-revenue analysis, EPA found that no more than 0.1 percent of offices, mostly in the lower revenue ranges, would potentially incur costs in excess of 3 percent of revenue. The two financial ratios reported in Tables IX–3 and IX–4 show that the final rule will not cause dental offices to encounter difficulty in financing initial spending on capital costs of the final rule. Based on the combined results of the three analyses and that EPA had no data since proposal to suggest otherwise, EPA determined that the final rule is economically achievable. Regarding large offices, EPA notes that, due to a lack of data, the economic impact analyses did not include large institutional offices. EPA did not receive comments indicating large offices would be impacted more or less than other dental offices subject to this rule. Given the results of the economic analysis performed on a range of office sizes indicating that the rule is economically achievable, EPA finds the rule would similarly be achievable for large institutional offices.

EPA determined that the final pretreatment standard for new sources will not be a barrier to entry. EPA relied on data describing the equipment needs and costs for starting a dental practice as compiled in Safety Net Dental Clinic Manual, prepared by the National Maternal & Child Oral Health Resource Center at Georgetown University (see DCN DA00143). Information from the Georgetown Manual demonstrates that the amalgam separator capital costs (based on costs for existing model offices as described in Section VII) comprised 0.2 percent to 0.3 percent of the cost of starting a dental practice as shown in Table IX–6 and, therefore, does not pose a barrier to entry.

TABLE IX–6—INITIAL SPENDING AS PERCENTAGE OF ESTIMATED DENTAL OFFICE START-UP COSTS

Number of chairs	Percent
1–2 chairs	0.3
3 chairs	0.3
4 chairs	0.3
5 chairs	0.2
6 chairs	0.3
7 chairs	0.3
8 chairs	0.3
9 chairs	0.3
Weighted Average	0.3

X. Cost-Effectiveness Analysis

EPA often uses cost-effectiveness analysis in the development and revision of ELGs to evaluate the relative efficiency of alternative regulatory options in removing toxic pollutants from effluent discharges to our nation's waters. Although not required by the CWA, and not a determining factor for establishing PSES or PSNS, cost-effectiveness analysis can be a useful

tool for describing regulatory options that address toxic pollutants.

EPA defines the cost-effectiveness of a regulatory option as the incremental annual cost (in 1981 constant dollars to facilitate comparison to ELGs for other industrial categories promulgated over different years) per incremental toxic-weighted pollutant removals for that option. For more information about the methodology, data, and results, see Chapter 12 of the TEDD. EPA determines toxic-weighted pollutant removals for a particular pollutant by multiplying the number of pounds of a pollutant removed by an option by a toxic weighting factor (TWF). The toxic weighting factor for each pollutant measures its toxicity relative to copper,[24] with more toxic pollutants having higher toxic weights. The use of toxic weights allows EPA to express the removals of different pollutants on a constant toxicity basis as toxic-pound-equivalents (lb-eq). In the case of indirect dischargers, the removal also accounts for the effectiveness of treatment at POTWs and reflects the toxic-weighted pounds after POTW treatment. The TWFs for the pollutants of concern are shown in Table X–1.

TABLE X–1—TOXIC WEIGHTING FACTORS FOR POLLUTANTS IN DENTAL AMALGAM

Mercury	110
Silver	16.47
Tin	0.301
Copper	0.623
Zinc	0.047

The costs used in the cost-effectiveness analyses are the estimated annual pre-tax costs described in Section IX, restated in 1981 dollars as a convention to allow comparisons with the reported cost effectiveness of other effluent guidelines. Collectively, the final PSES requirements have a cost-effectiveness ratio of $190–$195/lb-equivalent as shown in Table X–2 below. This cost-effectiveness ratio falls within the range of cost-effectiveness ratios for PSES requirements in other industries. A review of approximately 25 of the most recently promulgated or revised categorical pretreatment standards shows PSES cost-effectiveness ranges from less than $1/lb-equivalent (Inorganic Chemicals) to $380/lb-equivalent (Transportation Equipment Cleaning) in 1981 dollars.

TABLE X–2—PSES COST EFFECTIVENESS ANALYSIS

Final option	Pre-tax total annualized costs ($1981 M)	Removals (lbs-eq)	Average cost effectiveness
Colorado Survey	$23.5	123,552	$190
ADA National Survey	24.1	123,552	195

XI. Environmental Assessment

A. Environmental Impacts

EPA conducted a literature review concerning potential environmental impacts associated with mercury in dental amalgam discharged to surface water by POTWs (DCN DA00148). As discussed above, studies indicate that dental offices are the largest source of mercury entering POTWs. The total annual baseline discharge of dental mercury to POTWs is approximately 10,239 pounds (5.1 tons): 10,198 pounds are in the form of solid particles (99.6 percent) and 41 pounds (0.4 percent) are dissolved in the wastewater (DCN DA00018). Through POTW treatment, approximately 90 percent of dental mercury is removed from the wastewater and transferred to sewage sludge. The 10 percent of dental mercury not removed by POTW treatment is discharged to surface water. EPA estimates that POTWs annually discharge approximately 1,003 pounds of dental mercury nationwide.

The CWA regulations known as *Standards for Use and Disposal of Sewage Sludge,* 40 CFR part 503, control the land application, surface disposal, and incineration of sewage sludge generated by POTWs. Of the 11.2 billion dry pounds of sewage sludge generated annually, about 60 percent, or 6.7 billion pounds, are treated to produce biosolids for beneficial use as a soil amendment and applied to about 0.1 percent of agricultural lands in the United States (DCN DA00257). Approximately 5,500 pounds per year of dental mercury are contained in land-applied biosolids.

Approximately 18 percent, or 2 billion pounds, of the sewage sludge generated annually by POTWs are surface disposed in sewage sludge mono-fills or municipal landfills. Approximately 1,700 pounds per year of dental mercury are contained in surface disposed sewage sludge. Pollutant limits and monitoring requirements for surface disposed sewage sludge mono-fills are set by 40 CFR part 503 and by 40 CFR part 258 for municipal landfills. There may be additional state or local regulations that are more stringent than the federal biosolids regulations.

The remaining 22 percent, or 2.5 billion pounds, of sewage sludge generated annually by POTWs is disposed of through incineration. Approximately 2,000 pounds per year of dental mercury are contained in incinerated sewage sludge. 40 CFR part 503, subpart E sets requirements for the incineration of mercury and other toxic metals in sludge. For mercury, subpart E provides that incineration of sludge must meet the requirements of the National Emissions Standards for Mercury in subpart E of 40 CFR part 61.

Environmental assessment of impacts associated with POTW discharges of dental mercury is complicated by uncertainties about the fate and transport of mercury in aquatic environments. The elemental form of mercury used in dentistry has low water solubility and is not readily absorbed when ingested by humans, fish, or wildlife. However, elemental mercury may be converted into highly toxic methylmercury in aquatic environments by certain forms of anaerobic sulfate-reducing bacteria. Methylmercury has high potential to become increasingly concentrated up through aquatic food chains as larger fish eat smaller fish.

[24] When EPA first developed TWFs in 1981, it chose the copper freshwater chronic aquatic life criterion of 5.6 µg/L as the benchmark scaling factor for deriving TWFs because copper was a common and well-studied toxic chemical in industrial waste streams. Consequently, the basic equation for deriving the TWF for any chemical is: TWF = 5.6 µg/L/Aquatic Life Value (µg/L) + 5.6 µg/L/Human Health Value (µg/L). The chronic freshwater aquatic life criterion for copper, however, has been revised three times since it was first published in 1980 due to advances in the scientific understanding of its toxic effects. Thus, when calculating the TWF for copper, EPA normalizes the 1998 chronic freshwater aquatic life copper criterion of 9.0 µg/L to the original 1980 copper criterion of 5.6 µg/L by dividing 5.6 µg/L by 9.0 µg/L and adding the quotient to 5.6 µg/L divided by the copper human health value of 4444 µg/L, which results in a copper TWF of 0.623.

Fish commonly eaten by humans may have methylmercury levels 100,000 times that of ambient water. The neurological effects of consumption of methylmercury-contaminated fish are well documented. Developmental effects to fetuses, infants, children, and fish consumption by women of childbearing age are of special concern. Neurological effects from predation of methylmercury-contaminated fish have been documented to occur in wild populations of fish, birds, and mammals in many areas of the United States (DCN DA00202). A plausible link has been identified between anthropogenic sources of mercury in the United States and methylmercury in fish. However, fish methylmercury concentrations also result from existing background concentrations of mercury which may consist of mercury from natural sources and atmospheric deposition of mercury in the United States from sources in other countries. Given the current scientific understanding of the environmental fate and transport of mercury, it is not possible to quantify how much of the methylmercury in fish consumed by the U.S. population is contributed by U.S. emissions relative to international mercury sources or natural mercury sources.

EPA was unable to assess the specific environmental impacts of dental mercury discharged by POTWs due to insufficient data needed to evaluate several fundamental factors about the discharge, fate, and transport of dental mercury in aquatic environments, including: the degree and geographic extent of dental mercury methylation in aquatic environments, the amount of methylated dental mercury that is taken up by fish and wildlife, the human consumption rates of fish contaminated with methylated dental mercury, and the extent and magnitude of naturally-occurring mercury in aquatic environments.

B. Environmental Benefits

While EPA did not perform a quantitative environmental benefits analysis of the final rule, due to insufficient data about the aquatic fate and transport of dental mercury discharged by POTWs, EPA was able to assess the qualitative environmental benefits based on existing information. For example, EPA identified studies that show that decreased point-source discharges of mercury to surface water result in lower methylmercury concentrations in fish. Moreover, several studies quantify economic benefits from improved human health and ecological conditions resulting from lower fish concentrations of methylmercury (DCN DA00148). The final pretreatment standards will produce human health and ecological benefits by reducing the estimated annual nationwide POTW discharge of dental mercury to surface water from 1,003 pounds to 11 pounds.

XII. Non-Water Quality Environmental Impacts Associated With the Technology Basis of the Rule

Eliminating or reducing one form of pollution may cause other environmental problems. Sections 304(b) and 306 of the Clean Water Act require EPA to consider non-water quality environmental impacts (including energy requirements) associated with effluent limitations guidelines and standards. To comply with these requirements, EPA considered the potential impact of the technology basis on energy consumption, air pollution, and solid waste generation. As shown below, EPA anticipates that the rule would produce minimal non-water quality environmental impacts and as such determined they are acceptable. Additional information about the analysis of these non-water quality impacts is contained in the TEDD.

A. Energy Requirements

Net energy consumption considers the incremental electrical requirements associated with operating and maintaining dental amalgam separators used in combination with BMPs that form the technology basis for the standards. As described in Section V, most amalgam separators use sedimentation, either alone or in conjunction with filtration to remove solids in the waste stream. Most separators rely on gravity or the suction of the existing vacuum system to operate, and do not require an additional electrical power source. As noted in Section V, some separators have warning indicators that require a battery or power source. EPA does not anticipate this would pose any considerable energy requirements. Moreover, the addition of an amalgam separator is likely to reduce energy consumption at dental offices that do not currently employ an amalgam separator as it will prevent small particles from impeding the vacuum pump impeller. A clean impeller is more efficient than a dirty impeller, and thus will draw less energy (DCN DA00465). Upon consideration of all of these factors, EPA concludes there will be no significant energy requirements associated with this final rule.

B. Air Emissions

Unbound mercury is highly volatile and can easily evaporate into the atmosphere. An estimated 99.6 percent of dental mercury discharges are in solid bound form; *i.e.* elemental mercury bound to amalgam particles (DCN DA00018). Because the majority of dental mercury is bound to solid particles, it likely will not volatize to the atmosphere. Therefore, EPA expects the final PSES and PSNS will not pose any increases in air pollution.

C. Solid Waste Generation

In the absence of amalgam separators, a portion of the amalgam rinsed into chair-side drains is collected by chair-side traps. The remainder is discharged to the POTW where the vast majority is removed from the wastewater and becomes part of the POTW sludge that may be land-applied, disposed of in landfills or mono-fills, or incinerated. EPA expect the final rule to increase the use of amalgam separators nationwide by one and a half times with a corresponding increase in collection and recycling of used amalgam from the spent separator canisters. EPA expects the operation and maintenance requirements associated with the amalgam separator compliance option included in the final rule will further promote recycling as the primary means of amalgam waste management, because many amalgam separator manufactures and dental office suppliers have begun offering waste handling services that send dental amalgam waste to retorting and recycling facilities. Nationally, EPA expects less dental amalgam will be discharged to POTWs leading to reductions in the amount of mercury discharged to surface waters and land-applied, landfilled, or released to the air during incineration of sludge. Instead, EPA expects that the waste will be collected in separator canisters and recycled. After the amalgam containing waste has been recycled, the canisters are either recycled or landfilled. For purposes of assessing the incremental solid waste generation, EPA conservatively assumes all of the canisters are landfilled. EPA finds that if each dental office generated an average of 2 pounds of spent canisters per year, the total mass of solid waste generated would still comprise less than 0.0001 percent of the 254 million tons of solid waste generated by Americans annually (DCN DA00496). Based on this evaluation of incremental solid waste generation, EPA concludes there will not be a significant incremental non-water quality impact associated with

solid waste generation as a result of this final rule.

XIII. Standards for Reference

This rule references standards from the American National Standards Institute/American Dental Association and the International Organization for Standardization, and in compliance with the National Technology Transfer and Advancement Act (see Section XIV). They are available either at EPA's Water Docket (see **ADDRESSES** section above) for inspection, or on their respective Web sites to everyone at a cost determined by the respective Web site, generally from $100 to $150. The cost of obtaining these standards is not a significant financial burden for a discharger or environmental laboratory, making the standards reasonably available. The individual standards are discussed in greater detail below.

The installation, operation, and maintenance of one or more amalgam separators compliant with either the ADA 2009 standard with the 2011 addendum, or the ISO standard when removing dental amalgam solids from all amalgam process wastewater:

- ANSI/ADA Specification No. 108:2009, American National Standard/ American Dental Association Specification No. 108 Amalgam Separators.
- ANSI/ADA Specification No. 108:2009 Addendum, American National Standard/American Dental Association Specification No. 108 Amalgam Separators, Addendum.
- International Standard ISO 11143;2008, Dentistry—Amalgam Separators.

XIV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

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 because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket. The economic analysis is available in the docket (DCN DA00458) and is briefly summarized in Section IX. The benefits are summarized in Section XI.

B. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2514.02. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

EPA estimates it would take a total annual average of 402,000 hours and $7.2 million for affected dental offices to collect and report the information required in the final rule. This estimate includes effort for each dental office associated with completing a one-time compliance report. EPA based this estimate on average labor rates from the Bureau of Labor Statistics for the dental office personnel involved in collecting and reporting the information required. EPA estimates it would take a total annual average of 34,000 hours and $2.02 million for Control Authorities to review the information submitted by dental offices. EPA estimates that there would be no start-up or capital costs associated with the information described above. Burden is defined at 5 CFR 1320(b).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce the approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities in this final rule.

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. The small entities subject to the requirements of this action are defined as: (1) A small business in the Dental Office sector (NAICS 621210) with annual receipts of 7.5 million dollars or less (based on SBA size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

The Agency has determined that 116,014 dental offices out of 116,720 dental offices potentially subject to this final rule meet the small business definition. EPA's analysis of projected impacts on small dental offices is described in detail in Section IX. EPA projects less than 1 percent of 116,720 affected dental offices would incur compliance costs exceeding 1 percent of revenue and no more than 0.2 percent would incur compliance costs exceeding 3 percent of revenue.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this final rule on small entities. First, this final rule will allow dental offices with existing separators to satisfy the requirements for a period of up to 10 years. Second, EPA significantly reduced the rule's reporting requirements for all affected dental offices as compared to the reporting requirements for other industries with categorical pretreatment standards.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The annual cost of the final rule is $59 to $61 million; thus, this final rule is not subject to the requirements of sections 202 or 205 of UMRA.

This final rule is also not subject to the requirements of section 203 of UMRA, because it contains no regulatory requirements that may significantly or uniquely affect small governments. EPA has not identified any dental offices that are owned by small governments. While this final rule impacts government entities required to administer pretreatment standards, small governments will generally not be affected. By statute, a small government jurisdiction is defined as a government of a city, county, town, school district or special district with a population of less than 50,000 (5 U.S.C 601). Control authorities are responsible for oversight and administration associated with this final rule. A POTW is required to become a Control Authority when it (or a combination of POTWs operated by the same authority) has a design flow of at least 5 million gallons per day and receives pollutants from industrial users that would pass through or interfere with the operations and cause a violation of the POTW's NPDES permit. The average water use per person is 100 gallons per day so a POTW with a

population less than 50,000 would likely have a flow less than 5 MGD. Therefore, EPA does not expect small government owned POTWs to be required to become a Control Authority. EPA is aware that some small POTWs have approved pretreatment programs so they serve as a Control Authority. To the extent small POTWs with pre-existing approved pretreatment programs receive dental discharges subject to this rule, they would incur some incremental oversight requirements as described in Section VI. However, EPA expects such cases to be limited.

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.

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

This final rule does not have tribal implications, as specified in Executive Order 13175. It does not have substantial direct effects on Tribal governments, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. This final rule contains no Federal mandates for Tribal governments and does not impose any enforceable duties on Tribal governments. Thus, Executive Order 13175 does not apply to this final rule.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not project the environmental health or safety risks addressed by this action present a disproportionate risk to children. This final rule will reduce the amount of mercury from dental amalgam entering POTW's and eventually the nation's waters, which will reduce impacts to the neurological development of children.

H. Executive Order 13211: Energy Effects

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. EPA determined that any additional energy usage would be insignificant to the total energy usage of Dental Offices and total annual U.S. energy consumption.

I. National Technology Transfer and Advancement Act

This final rule involves technical standards. The Agency decided to use the American National Standards Institute (ANSI) American National Standard/American Dental Association (ADA) Specification 108 for Amalgam Separators (2009) with Technical Addendum (2011) or the International Organization for Standardization (ISO) 11143 Standard (2008) or the International Organization for Standardization (ISO) efficiency standards for amalgam separators (ISO 11143) developed in 1999 and updated in 2008. One approach to meet the standards in this rule is to install and operate an amalgam separator(s) compliant with one of these standards or their equivalent. These voluntary standard setting organizations established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam mercury using specified test procedures in a laboratory setting. They also include requirements for instructions for use and operation and maintenance.

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

EPA determined that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). While EPA was unable to perform a detailed environmental justice analysis because it lacks data on the location of POTWs to which dental discharges currently occur, this final rule will increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This final rule will reduce the amount of mercury from dental amalgam entering POTW's and eventually the nation's waters, to benefit all of society, including minority communities.

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 441

Environmental protection, Dental, Dental office, Dentist, Mercury, Pretreatment, Waste treatment and disposal, Water pollution control.

Dated: June 9, 2017.

Michael H. Shapiro,

Acting Assistant Administrator.

Therefore, 40 CFR part 441 is amended by adding part 441 to read as follows:

PART 441—DENTAL OFFICE POINT SOURCE CATEGORY

Sec.

Authority: 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342, and 1361. 42 U.S.C. 13101–13103.

§ 441.10 Applicability.

(a) Except as provided in paragraphs (c), (d), and (e) of this section, this part applies to dental dischargers.

(b) Unless otherwise designated by the Control Authority, dental dischargers subject to this part are not Significant Industrial Users as defined in 40 CFR part 403, and are not ''Categorical Industrial Users'' or ''industrial users subject to categorical pretreatment standards'' as those terms and variations are used in 40 CFR part 403, as a result of applicability of this rule.

(c) This part does not apply to dental dischargers that exclusively practice one or more of the following dental specialties: Oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics.

(d) This part does not apply to wastewater discharges from a mobile unit operated by a dental discharger.

(e) This part does not apply to dental dischargers that do not discharge any amalgam process wastewater to a POTW, such as dental dischargers that collect all dental amalgam process wastewater for transfer to a Centralized Waste Treatment facility as defined in 40 CFR part 437.

(f) Dental Dischargers that do not place dental amalgam, and do not remove amalgam except in limited emergency or unplanned, unanticipated circumstances, and that certify such to

the Control Authority as required in § 441.50 are exempt from any further requirements of this part.

§ 441.20 General definitions.

For purposes of this part:

(a) *Amalgam process wastewater* means any wastewater generated and discharged by a dental discharger through the practice of dentistry that may contain dental amalgam.

(b) *Amalgam separator* means a collection device designed to capture and remove dental amalgam from the amalgam process wastewater of a dental facility.

(c) *Control Authority* is defined in 40 CFR 403.3(f).

(d) *Dental amalgam* means an alloy of elemental mercury and other metal(s) that is used in the practice of dentistry.

(e) *Dental Discharger* means a facility where the practice of dentistry is performed, including, but not limited to, institutions, permanent or temporary offices, clinics, home offices, and facilities owned and operated by Federal, state or local governments, that discharges wastewater to a publicly owned treatment works (POTW).

(f) *Duly Authorized Representative* is defined in 40 CFR 403.12(l)(3).

(g) *Existing Sources* means a dental discharger that is not a new source.

(h) *Mobile unit* means a specialized mobile self-contained van, trailer, or equipment used in providing dentistry services at multiple locations.

(i) *New Sources* means a dental discharger whose first discharge to a POTW occurs after July 14, 2017.

(j) *Publicly Owned Treatment Works* is defined in 40 CFR 403.3(q).

§ 441.30 Pretreatment standards for existing sources (PSES).

No later than July 14, 2020, any existing source subject to this part must achieve the following pretreatment standards:

(a) Removal of dental amalgam solids from all amalgam process wastewater by one of the following methods:

(1) Installation, operation, and maintenance of one or more amalgam separators that meet the following requirements:

(i) Compliant with either the American National Standards Institute (ANSI) American National Standard/ American Dental Association (ADA) Specification 108 for Amalgam Separators (2009) with Technical Addendum (2011) or the International Organization for Standardization (ISO) 11143 Standard (2008) or subsequent versions so long as that version requires amalgam separators to achieve at least a 95% removal efficiency. Compliance must be assessed by an accredited testing laboratory under ANSI's accreditation program for product certification or a testing laboratory that is a signatory to the International Laboratory Accreditation Cooperation's Mutual Recognition Arrangement. The testing laboratory's scope of accreditation must include ANSI/ADA 108–2009 or ISO 11143.

(ii) The amalgam separator(s) must be sized to accommodate the maximum discharge rate of amalgam process wastewater.

(iii) A dental discharger subject to this part that operates an amalgam separator that was installed at a dental facility prior to June 14, 2017, satisfies the requirements of paragraphs (a)(1)(i) and (ii) of this section until the existing separator is replaced as described in paragraph (a)(1)(v) of this section or until June 14, 2017, whichever is sooner.

(iv) The amalgam separator(s) must be inspected in accordance with the manufacturer's operating manual to ensure proper operation and maintenance of the separator(s) and to confirm that all amalgam process wastewater is flowing through the amalgam retaining portion of the amalgam separator(s).

(v) In the event that an amalgam separator is not functioning properly, the amalgam separator must be repaired consistent with manufacturer instructions or replaced with a unit that meets the requirements of paragraphs (a)(i) and (ii) of this section as soon as possible, but no later than 10 business days after the malfunction is discovered by the dental discharger, or an agent or representative of the dental discharger.

(vi) The amalgam retaining units must be replaced in accordance with the manufacturer's schedule as specified in the manufacturer's operating manual or when the amalgam retaining unit has reached the maximum level, as specified by the manufacturer in the operating manual, at which the amalgam separator can perform to the specified efficiency, whichever comes first.

(2) Installation, operation, and maintenance of one or more amalgam removal device(s) other than an amalgam separator. The amalgam removal device must meet the following requirements:

(i) Removal efficiency of at least 95 percent of the mass of solids from all amalgam process wastewater. The removal efficiency must be calculated in grams recorded to three decimal places, on a dry weight basis. The removal efficiency must be demonstrated at the maximum water flow rate through the device as established by the device manufacturer's instructions for use.

(ii) The removal efficiency must be determined using the average performance of three samples. The removal efficiency must be demonstrated using a test sample of dental amalgam that meets the following particle size distribution specifications: 60 percent by mass of particles that pass through a 3150 μm sieve but which do not pass through a 500 μm sieve, 10 percent by mass of particles that pass through a 500 μm sieve but which do not pass through a 100 μm sieve, and 30 percent by mass of particles that pass through a 100 μm sieve. Each of these three specified particle size distributions must contain a representative distribution of particle sizes.

(iii) The device(s) must be sized to accommodate the maximum discharge rate of amalgam process wastewater.

(iv) The devices(s) must be accompanied by the manufacturer's manual providing instructions for use including the frequency for inspection and collecting container replacement such that the unit is replaced once it has reached the maximum filling level at which the device can perform to the specified efficiency.

(v) The device(s) must be inspected in accordance with the manufacturer's operation manual to ensure proper operation and maintenance, including confirmation that amalgam process wastewater is flowing through the amalgam separating portion of the device(s).

(vi) In the event that a device is not functioning properly, it must be repaired consistent with manufacturer instructions or replaced with a unit that meets the requirements of paragraphs (a)(2)(i) through (iii) of this section as soon as possible, but no later than 10 business days after the malfunction is discovered by the dental discharger, or an agent or representative of the dental discharger.

(vii) The amalgam retaining unit(s) of the device(s) must be replaced as specified in the manufacturer's operating manual, or when the collecting container has reached the maximum filling level, as specified by the manufacturer in the operating manual, at which the amalgam separator can perform to the specified efficiency, whichever comes first.

(viii) The demonstration of the device(s) under paragraphs (a)(2)(i) through (iii) of this section must be documented in the One-Time Compliance Report.

(b) Implementation of the following best management practices (BMPs):

(1) Waste amalgam including, but not limited to, dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices, must not be discharged to a POTW.

(2) Dental unit water lines, chair-side traps, and vacuum lines that discharge amalgam process wastewater to a POTW must not be cleaned with oxidizing or acidic cleaners, including but not limited to bleach, chlorine, iodine and peroxide that have a pH lower than 6 or greater than 8.

(c) All material is available for inspection at EPA's Water Docket, EPA West, 1301 Constitution Avenue NW., Room 3334, Washington, DC 20004, Telephone: 202–566–2426, and is available from the sources listed below.

(1) The following standards are available from the American Dental Association (ADA), 211 East Chicago Ave., Chicago IL 60611–2678, Telephone 312–440–2500, *http://www.ada.org.*

(i) ANSI/ADA Specification No. 108:2009, American National Standard/American Dental Association Specification No. 108 Amalgam Separators. February 2009.

(ii) ANSI/ADA Specification No. 108:2009 Addendum, American National Standard/American Dental Association Specification No. 108 Amalgam Separators, Addendum. November 2011.

(2) The following standards are available from the American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, Telephone 212–642–4900, *http://webstore.ansi.org.*

(i) International Standard ISO 11143:2008, Dentistry—Amalgam Separators. Second edition, July 1, 2008.

(ii) [Reserved]

§ 441.40 Pretreatment standards for new sources (PSNS).

As of July 14, 2017, any new source subject to this part must comply with the requirements of § 441.30(a) and (b) and the reporting and recordkeeping requirements of § 441.50.

§ 441.50 Reporting and recordkeeping requirements.

(a) Dental Dischargers subject to this part must comply with the following reporting requirements in lieu of the otherwise applicable requirements in 40 CFR 403.12(b), (d), (e), and (g).

(1) *One-Time Compliance Report deadlines.* For existing sources, a One-Time Compliance Report must be submitted to the Control Authority no later than October 12, 2020, or 90 days after a transfer of ownership. For new sources, a One-Time Compliance Report must be submitted to the Control Authority no later than 90 days following the introduction of wastewater into a POTW.

(2) *Signature and certification.* The One-Time Compliance Report must be signed and certified by a responsible corporate officer, a general partner or proprietor if the dental discharger is a partnership or sole proprietorship, or a duly authorized representative in accordance with the requirements of 40 CFR 403.12(l).

(3) *Contents.* (i) The One-Time Compliance Report for dental dischargers subject to this part that do not place or remove dental amalgam as described at § 441.10(f) must include the: facility name, physical address, mailing address, contact information, name of the operator(s) and owner(s); and a certification statement that the dental discharger does not place dental amalgam and does not remove amalgam except in limited circumstances.

(ii) The One-Time Compliance Report for dental dischargers subject to the standards of this part must include:

(A) The facility name, physical address, mailing address, and contact information.

(B) Name(s) of the operator(s) and owner(s).

(C) A description of the operation at the dental facility including: The total number of chairs, the total number of chairs at which dental amalgam may be present in the resulting wastewater, and a description of any existing amalgam separator(s) or equivalent device(s) currently operated to include, at a minimum, the make, model, year of installation.

(D) Certification that the amalgam separator(s) or equivalent device is designed and will be operated and maintained to meet the requirements specified in § 441.30 or § 441.40.

(E) Certification that the dental discharger is implementing BMPs specified in § 441.30(b) or § 441.40(b) and will continue to do so.

(F) The name of the third-party service provider that maintains the amalgam separator(s) or equivalent device(s) operated at the dental office, if applicable. Otherwise, a brief description of the practices employed by the facility to ensure proper operation and maintenance in accordance with § 441.30 or § 441.40.

(4) *Transfer of ownership notification.* If a dental discharger transfers ownership of the facility, the new owner must submit a new One-Time Compliance Report to the Control Authority no later than 90 days after the transfer.

(5) *Retention period.* As long as a Dental Discharger subject to this part is in operation, or until ownership is transferred, the Dental Discharger or an agent or representative of the dental discharger must maintain the One-Time Compliance Report required at paragraph (a) of this section and make it available for inspection in either physical or electronic form.

(b) Dental Dischargers or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form, for a minimum of three years:

(1) Documentation of the date, person(s) conducting the inspection, and results of each inspection of the amalgam separator(s) or equivalent device(s), and a summary of follow-up actions, if needed.

(2) Documentation of amalgam retaining container or equivalent container replacement (including the date, as applicable).

(3) Documentation of all dates that collected dental amalgam is picked up or shipped for proper disposal in accordance with 40 CFR 261.5(g)(3), and the name of the permitted or licensed treatment, storage or disposal facility receiving the amalgam retaining containers.

(4) Documentation of any repair or replacement of an amalgam separator or equivalent device, including the date, person(s) making the repair or replacement, and a description of the repair or replacement (including make and model).

(5) Dischargers or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form the manufacturers operating manual for the current device.

[FR Doc. 2017–12338 Filed 6–12–17; 11:15 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 15, 80, 90, 97, and 101

[ET Docket No. 15–99; FCC 17–33]

WRC–12 Implementation Report and Order

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission implemented allocation changes from the World Radiocommunication Conference