AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 79 Wednesday,
No. 204 October 22, 2014

Part III

Environmental Protection Agency

40 CFR Parts 403 and 441
Effluent Limitations Guidelines and Standards for the Dental Category; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 403 and 441

[EPA–HQ–OW–2014–0693; FRL–9911–63–OW]

RIN 2040–AF26

Effluent Limitations Guidelines and Standards for the Dental Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing technology-based pretreatment standards under the Clean Water Act (CWA) for discharges of pollutants into publicly owned treatment works (POTWs) from existing and new dental practices that discharge dental amalgam. Dental amalgam contains mercury in a highly concentrated form that is relatively easy to collect and recycle. Dental offices are the main source of mercury discharges to POTWs. Mercury is a persistent and bioaccumulative pollutant in the environment with well-documented neurotoxic effects on humans. Mercury pollution is widespread and comes from many diverse sources such as air deposition from municipal and industrial incinerators and combustion of fossil fuels. Mercury easily becomes diffuse in the environment and mercury pollution is a global problem. Removing mercury from the waste stream when it is in a concentrated and easy to handle form like in waste dental amalgam is an important and commonsense step to take to prevent that mercury from being released back into the environment where it can become diffuse and a hazard to humans.

The proposal would require dental practices to comply with requirements for controlling the discharge of mercury and other metals in dental amalgam into POTWs based on the best available technology or best available demonstrated control technology. Specifically, the requirements would be based on the use of amalgam separators and best management practices (BMPs). Amalgam separators are a practical, affordable and readily available technology for capturing mercury and other metals before they are discharged into sewers and POTWs. EPA is also proposing to amend selected parts of the General Pretreatment Regulations to streamline oversight requirements for the dental sector. EPA expects compliance with this proposed rule would reduce the discharge of metals to POTWs by at least 8.8 tons per year, about half of which is mercury. EPA estimates the annual cost of the proposed rule would be $44 to $49 million.

DATES: Comments on this proposed rule must be received on or before December 22, 2014. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions must be received by the Office of Management and Budget (OMB) on or before November 21, 2014. EPA will conduct a public hearing on November 10, 2014 at 1 p.m. in the William J. Clinton Building—East Room 1153, 1201 Constitution Avenue NW., Washington, DC.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OW–2014–0693 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: OW-Docket@epa.gov,* Attention Docket ID number EPA–HQ–OW–2014–0693.
- *Mail:* Water Docket, Environmental Protection Agency, Mail code: 4203M, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Attention Docket ID number EPA–HQ–OW–2014–0693. Please include a total of three copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.
- *Hand Delivery:* Water Docket, EPA Docket Center, EPA West Building Room 3334, 1301 Constitution Ave. NW., Washington, DC, Attention Docket ID Number EPA–HQ–OW–2014–0693. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information by calling 202–566–2426.

Instructions: Direct your comments to docket ID number EPA–HQ–OW–2014–0693. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. A detailed record index, organized by subject, is available on EPA's Web site at *http://water.epa.gov/scitech/wastetech/guide/dental/index.cfm.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy 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.

Pretreatment Hearing Information: EPA will conduct a public hearing on the proposed pretreatment standards on November 10, 2014 at 1:00 p.m. in the William Jefferson Clinton Building EPA East Building—East Room 1153, 1201 Constitution Avenue NW., Washington, DC. No registration is required for this public hearing. During the pretreatment hearing, the public will have an opportunity to provide oral comment to EPA on the proposed pretreatment standards. EPA will not address any issues raised during the hearing at that time but these comments will be included in the public record for the rule. For security reasons, we request that you bring photo identification with you to the meeting. Also, if you let us know in advance of your plans to attend, it will expedite the process of

signing in. Seating will be provided on a first-come, first-served basis. Please note that parking is very limited in downtown Washington, and use of public transit is recommended. The EPA Headquarters complex is located near the Federal Triangle Metro station. Upon exiting the Metro station, walk east to 12th Street. On 12th Street, walk south to Constitution Avenue. At the corner, turn right onto Constitution Avenue and proceed to the EPA East Building entrance.

FOR FURTHER INFORMATION CONTACT: Damon Highsmith, Engineering and Analysis Division (4303T), Office of Water, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone: 202–566–2504; email: *highsmith.damon@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Regulated Entities
II. How To Submit Comments
III. Supporting Documentation
IV. Overview
V. Legal Authority
VI. Purpose and Summary of Proposed Rule
VII. Solicitation of Data and Comments
VIII. Background
IX. Description of the Dental Industry
X. Summary of Data Collection
XI. Wastewater Characteristics, Dental Office Configurations, and Technology Options
XII. Scope/Applicability
XIII. Subcategorization
XIV. Proposed Regulation
XV. Technology Costs
XVI. Economic Impact Analysis
XVII. Pollutant Reductions to POTWs and Surface Waters
XVIII. Cost Effectiveness
XIX. Environmental Assessment
XX. Non-Water Quality Environmental Impacts Associated With the Proposed Technology Basis
XXI. Implementation and Proposed Changes to General Pretreatment Regulations in 40 CFR Part 403
XXII. Statutory and Executive Order Reviews

I. 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 where mercury amalgam is placed or removed.	621210
States	Where they are the Control Authority [1]	221320
Municipalities	POTWs and other municipally owned facilities that receive pollutants from dental offices.	221320

This section is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this proposed action. 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 proposed action, you should carefully examine the applicability criteria listed in § 441.10 and the definitions in § 441.20 of this proposed rule and detailed further in Section XII of this preamble. If you still have questions regarding the proposed applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How To Submit Comments

The public may submit comments in written or electronic form. (see **ADDRESSES**). Electronic comments must be identified by the docket ID number EPA–HQ–OW–2014–0693 and must be submitted as a WordPerfect, MS Word or ASCII text file, avoiding the use of special characters and any form of encryption. EPA requests that any graphics included in electronic comments also be provided in hard-copy form. EPA also will accept comments and data on disks in the aforementioned file formats. Electronic comments received on this document may be filed online at many Federal Depository Libraries. No CBI should be sent by email.

III. Supporting Documentation

The proposed rule is supported by a number of documents including:

- Technical and Economic Development Document for Proposed Effluent Limitations Guidelines and Standards for the Dental Category (TEDD), Document No. EPA–821–R–14–006.

The TEDD summarizes the technical and economic analysis described in this document. The TEDD and additional records are available in the public record for this proposed rule and on EPA's Web site at *http://water.epa.gov/scitech/wastetech/guide/dental/index.cfm.* They are available in hard copy from the National Service Center for Environmental Publications (NSCEP), U.S. EPA/NSCEP, P.O. Box 42419, Cincinnati, Ohio 45242–2419, telephone 800–490–9198, *http://epa.gov/ncepihom.*

IV. Overview

The preamble describes the terms, acronyms, and abbreviations used in this document; the background documents that support these proposed regulations; the legal authority for the proposed rules; a summary of the options considered for the proposal; background information; and the technical and economic methodologies used by the Agency to develop these proposed regulations. This preamble also solicits comment and data on specific areas of interest.

V. Legal Authority

EPA is proposing 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.*

VI. Purpose and Summary of Proposed Rule

Across the United States, many states and POTWs (also referred to as municipal wastewater treatment plants) are working toward the goal of reducing discharges of mercury to POTWs. Mercury is a persistent and bioaccumulative pollutant with well-documented effects on human health. On November 6, 2013, the United States joined the Minamata Convention on Mercury, a new multilateral environmental agreement not yet in force 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

[1] See Section XXI for a definition of Control Authority.

measures for phasing down the use of mercury in dental amalgam, including promoting the use of best environmental practices in dental facilities 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.

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 Final Report (DCN DA00006) prepared by the National Association of Clean Water Agencies (NACWA), dentists are the main source of mercury discharges to POTWs. A study funded by the American Dental Association (ADA) published in 2005 estimated that 50% of mercury entering POTWs was contributed by dental offices (DCN DA00163). Mercury is discharged in the form of dental amalgam when dentists remove old amalgam fillings from cavities, and from excess amalgam removed when a dentist places a new filling.

EPA estimates that across the United States 4.4 tons of mercury from waste dental amalgam are collectively discharged into POTWs annually. Mercury at POTWs frequently partitions to the sludge, the solid material that remains after wastewater is treated. Mercury from amalgam can then make its way into the environment through the incineration, landfilling, or land application of sludge or through surface water discharge. Once deposited, certain microorganisms can change mercury into methylmercury, a highly toxic form of mercury that accumulates in fish, shellfish, and animals that eat fish. Fish and shellfish are the main sources of methylmercury exposure to humans.

Today's proposed pretreatment standards would control mercury discharges to POTWs by requiring dentists to reduce their discharge of dental amalgam to a level achievable through the use of the best available technology (a combination of amalgam separators and the use of BMPs. In order to simplify compliance with, and enforcement of, the numeric reduction requirements, the proposed rule would allow dentists to demonstrate compliance through the proper use of amalgam separators rather than through discharge monitoring. Removing concentrated sources of mercury waste opportunistically, such as through low-cost amalgam separators at dental offices (average annual cost per dental office: $700 [2]), is a common sense solution to managing mercury where it is most concentrated within the waste stream that would otherwise be released to air, land, and water.

Additionally, EPA is proposing to amend selected parts of the General Pretreatment Regulations (40 CFR part 403) in order to streamline permitting and oversight requirements specific to the dental sector. The number of dental offices that would likely be subject to national pretreatment standards is approximately ten times the current number of Categorical Industrial Users (CIUs). The proposed changes to 40 CFR part 403 reflect EPA's recognition that the current regulatory framework needs to be adjusted for the effective implementation and enforcement of these pretreatment requirements affecting the dental industry. When categorical pretreatment requirements apply to an industry, it creates certain oversight requirements. While other industries subject to categorical pretreatment requirements typically consist of tens to hundreds of facilities, the dental industry consists of approximately 100,000 facilities, making oversight of this large number of facilities subject to categorical pretreatment standards much more challenging.

VII. Solicitation of Data and Comments

EPA solicits comments on the proposed rule, including EPA's rationale as described in this preamble. EPA seeks comments on issues specifically identified in this document as well as any other issues that are not specifically addressed in this document. Comments are most helpful when accompanied by specific examples and supporting data. Specifically, EPA solicits information and data on the following topics.

1. Data demonstrating the effectiveness of polishing, or the use of sorbent columns after solids separation, in reducing mercury discharges from dental offices.

2. Data on costs, performance, affordability and availability of polishing in combination with amalgam separators.

3. Ways for dental offices to demonstrate compliance with this proposed rule, and how much reporting should be required.

4. Information on EPA's approach for addressing offices where no dental amalgam is applied or removed, and its approach for offices that already employ a separator (including cases where the separator was installed as a result of a program required by a state or other locality and where the separator has a certified removal efficiency that is lower than 99.0%).

5. Information on the frequency of emergency removals at dental offices that do not routinely place or remove amalgam.

6. EPA seeks comment on its approach for addressing offices where no dental amalgam is placed or removed except in limited emergency circumstances, and its approach for offices that have already installed an amalgam separator.

7. EPA proposes an inspection frequency of at least once per month to ensure proper operation and maintenance of the amalgam separator. EPA solicits comment on this frequency as well as others, and justifications for alternative approaches.

8. Data on the number of dentists in practices potentially subject to this rule that do not place or remove dental amalgam and on the number of dentists in practices excluded from the proposed rule such as oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, and prosthodontics. EPA also solicits comment on its estimate of the number of dentists in dental specialties that are not subject to this proposed rule.

9. Other technologies not discussed in this proposed rule that have demonstrated an ability to reduce discharges of mercury from dental offices and their associated costs.

10. Data regarding EPA's analysis of clinics and very large facilities.

11. EPA's proposed revisions to 40 CFR part 403, including revisions to create the DIU category, and the means of evaluating ongoing compliance for the purposes of maintaining the DIU designation.

12. Information about mobile facilities used to treat patients. EPA seeks information on the number, size, operation and financial characteristics of mobile facilities that offer dental treatment.

13. EPA's estimate of the number of large institutional practices, including large facilities operated by the Federal Government, and the characteristics (chair size, number of practitioners, currently employed mercury reduction approaches, incremental cost of proposed requirements) of these facilities.

14. Additional information on equipment needs and costs for starting a dental practice including information on the life of the dental equipment.

[2] This estimate is based on the average annualized cost for dentists that do not currently have an amalgam separator. See DCN DA00145.

15. Additional information on low revenue dental offices and if they could represent baseline closures (see discussion in Section XVI).

16. Additional information on the location and characteristics of low revenue dental offices ((1) single-dentist and/or part-time businesses that provide services as a subcontractor on an independent fee-for-service basis (2) non-profit groups, or (3) non-viable as for-profit businesses).

17. Information on requiring an efficiency that exceeds the ISO standard.

18. The proposal would greatly reduce potential requirements that would otherwise apply to control authorities with respect to dental dischargers. EPA solicits comments on its estimate of burden and costs associated with these reduced requirements. In particular, EPA solicits data from control authorities located in municipalities or states where similar mandatory dental amalgam reduction programs exist.

VIII. Background

A. Clean Water Act

Congress passed the Federal Water Pollution Control Act Amendments of 1972, also known as the Clean Water Act, 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 also authorizes EPA to establish national technology-based effluent limitations guidelines and standards (effluent guidelines or ELGs) for discharges from different categories of point sources, such as industrial, commercial, and public sources.

Congress recognized that regulating only those sources that discharge effluent directly into the nation's waters would not be sufficient to achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally-applicable pretreatment guidelines and standards that restrict pollutant discharges from facilities that discharge wastewater indirectly through sewers flowing to POTWs. (see CWA sections 304(g), 307(b) and (c), 33 U.S.C. 1314(g), and 1317(b) and (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers that may pass through, interfere with or are otherwise incompatible with POTW operations. Generally, pretreatment standards are designed to ensure that wastewaters from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local treatment limits applicable to their industrial indirect dischargers to satisfy any local requirements. (see 40 CFR 403.5).

Direct dischargers must comply with effluent limitations in NPDES permits. Indirect dischargers, who discharge through POTWs, must comply with pretreatment standards. Technology-based effluent limitations in NPDES permits 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. Additional limitations based on water quality standards (CWA sections 301(b)(1)(C) and 303) may also be included in the permit in certain circumstances. The ELGs are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

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); (2) toxic pollutants (e.g., toxic metals such as chromium, lead, mercury, nickel, and zinc; toxic organic pollutants such as benzene, benzo-a-pyrene, phenol, and naphthalene) as specified in CWA section 307 and; (3) non-conventional pollutants, those pollutants that are neither conventional nor toxic (e.g., ammonia-N, formaldehyde, and phosphorus).

B. Effluent Guidelines and Standards Program

Effluent limitations guidelines and standards are technology-based regulations that are developed by EPA for a category of dischargers. These regulations are based on the performance of control and treatment technologies. The legislative history of CWA section 304(b), describes the need to achieve progressively higher levels of control through research and development of new processes, modifications, replacement of obsolete plans and processes, and other improvements in technology, taking into account the cost of controls. Congress also directed that EPA not consider water quality impacts on individual water bodies as the guidelines are developed. See Statement of Senator Muskie (Oct. 4, 1972), reprinted in Legislative History of the Water Pollution Control Act Amendments of 1972, at 170. (U.S. Senate, Committee on Public Works, Serial No. 93–1, January 1973.)

There are standards applicable to direct dischargers (dischargers to surface waters), and standards applicable to indirect dischargers (discharges to publicly owned treatment works or POTWs). The standards relevant to this rulemaking are summarized here.

1. Best Available Technology Economically Achievable (BAT)

BAT effluent limitations guidelines apply to direct dischargers of toxic and nonconventional pollutants. In general, BAT effluent limitations guidelines represent the best economically achievable performance of facilities in the industrial subcategory or category. The factors considered in assessing BAT include 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. The Agency has considerable discretion in assigning the weight to be accorded these factors. An additional statutory factor considered in setting BAT is economic achievability. Generally, EPA determines economic achievability on the basis of total costs to the industry and the effect of compliance with BAT limitations on overall industry and subcategory financial conditions. Where existing performance is uniformly inadequate, BAT may reflect a higher level of performance than is currently being achieved based on technology transferred from a different subcategory or category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

2. New Source Performance Standards (NSPS)

NSPS reflect effluent reductions that are achievable based on the best available demonstrated control technology. 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 best available demonstrated control technology for all pollutants (that is, conventional, nonconventional, and priority 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.

3. Pretreatment Standards for Existing Sources (PSES)

Pretreatment standards apply to discharges of pollutants to POTWs rather than discharges to waters of the United States. Pretreatment Standards for Existing Sources are designed to prevent the discharge of pollutants 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.

The General Pretreatment Regulations, which set forth the framework for the implementation of categorical pretreatment standards, are found at 40 CFR part 403.

4. 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. The Agency typically considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

5. 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.'')

C. The National Pretreatment Program, 40 CFR Part 403

The General Pretreatment Regulations of 40 CFR part 403 establish responsibilities among federal, state, local government, industry, and the public to implement pretreatment standards to control pollutants that pass through or interfere with the POTW treatment processes or that can contaminate sewage sludge. The regulations, which have been revised numerous times since originally published in 1978, consist of 20 sections and seven appendices. The General Pretreatment Regulations use two terms describing oversight responsibilities under those regulations. One is the term Control Authority. The ''Control Authority'' refers to the POTW if the POTW has an approved Pretreatment Program, or the Approval Authority if the program has not been approved. The term Approval Authority describes the party with responsibility to administer the National Pretreatment Program, which is either a state with an approved state Pretreatment Program or, in a state without an approved Pretreatment Program, the EPA region for that state (40 CFR 403.3(f)). An approved Pretreatment Program is comprised of legal authorities, procedures, funding, local limits, enforcement response plan, and the list of significant industrial users (SIUs), together which the Control Authority uses to implement the General Pretreatment Regulations. The General Pretreatment Regulations apply to all nondomestic sources that introduce pollutants into a POTW. These sources of indirect discharges are more commonly referred to as Industrial Users (IUs). All IUs are subject to general pretreatment standards (40 CFR part 403), including a prohibition on discharges causing ''pass through'' or ''interference'' (*i.e.,* cause the POTW to violate its permits limits, or interfere with the operation of the POTW or the beneficial use of its sewage sludge). All POTWs with approved Pretreatment Programs must develop local limits to implement the general pretreatment standards. All other POTWs must develop such local limits where they have experienced ''pass through'' or ''interference'' and such a violation is likely to recur. There are approximately 1,500 POTWs with approved Pretreatment Programs and 13,500 small POTWs that are not required to develop and implement Pretreatment Programs.

D. State and Local Requirements

Currently, 12 states (Connecticut, Louisiana, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Oregon, Rhode Island, Vermont, and Washington) have implemented mandatory programs to reduce dental mercury discharges.[3] Additionally, at least 19 localities similarly have mandatory dental reduction pretreatment programs. These mandatory programs require the use of amalgam separators and BMPs. Removal efficiency requirements for separators in mandatory program jurisdictions vary from 95% to 99%. A full list of jurisdictions with mandatory separator requirements can be found in the TEDD for this proposed rulemaking.

Later in this document, EPA estimates costs and economic impacts for this proposed rule. In order to do so, EPA needed to estimate baseline compliance, or those dental offices that already have amalgam separators installed, and, therefore, would incur lower costs and impacts from the proposed rule. In order to estimate baseline compliance, EPA distributed the number of dental offices shown in Table IX–1 of Section IX by state,[4] based on the 2007 Economic Census. Because EPA has no data to indicate otherwise, EPA assumes 100% compliance in the 12 states that require amalgam separators. For states without mandatory programs, EPA assumed that 20% of dentists have voluntarily installed amalgam separators. As a result, EPA estimates approximately 40% of dental offices, nationally, have amalgam separators installed (DCN DA00146). EPA, however, welcomes data and comment on this assumption.

[3] New Mexico has a similar program that is scheduled to go into effect in 2015.

[4] Puerto Rico, the Virgin Islands, Pacific Islands and Tribal Nations are not included in this analysis.

E. 2008 Memorandum of Understanding on Reducing Mercury Discharges

In December 2008, EPA signed a Memorandum of Understanding (MOU) with the ADA and the NACWA to establish and monitor the effectiveness of a Voluntary Dental Amalgam Discharge Reduction Program. The purpose of the MOU is to encourage dental offices to voluntarily install and properly maintain amalgam separators, and recycle the collected amalgam waste. Although EPA has not conducted a formal evaluation of the effectiveness of the MOU, EPA is proposing National Pretreatment Standards to accomplish the goals of the MOU in a more predictable timeframe than a voluntary approach.

F. ADA BMPs and Support for a National Rulemaking

ADA encourages dentists to handle mercury and mercury amalgam in a manner that is consistent with ADA's ''Best Management Practices for Amalgam Waste.'' ADA's BMPs are designed to reduce the amount of mercury entering the environment. Practices encouraged by these BMPs include reducing the volume of bulk elemental mercury in dentists' offices, encouraging dentists to recycle amalgam to the greatest extent possible, preventing mercury from being disposed of in medical waste bags, and preventing amalgam from entering the wastewater stream. In 2007, ADA added the use of amalgam separators to their BMPs. See DCN DA00165.

In late 2010, ADA's Board of Directors adopted nine principles upon which ADA supported National Pretreatment Standards for dental facilities. See DCN DA00137.

IX. Description of the Dental Industry

The industry category that would be affected by this proposed 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 2007 Economic Census, there were 127,057 U.S. dental offices owned or operated by 121,048 dental firms.[5] Only 2% of all dental firms were multi-unit with the vast majority being single-unit. The growth of the number of dental offices has remained steady over the past decade with an average increase of 1% per year.

The industry includes mostly small businesses with an estimated 99.8% of all offices falling below the Small Business Administration (SBA) size standard ($7 million in annual revenue). Average revenues for offices were estimated at $739,280 per year with an average of 6.50 employees per establishment.

According to ADA data, approximately 80% of the dental industry engages in general dentistry. Approximately 20% are specialty dentists such as periodontics, orthodontics, radiology, maxillofacial surgery, endodontists, or prosthodontics (DCN DA00123).

One way to categorize dental offices is based on the number of chairs in each facility. The 2007 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, demonstrate distribution of dentist offices by number of chairs (DCN DA00141 and DCN DA00149). EPA used these two sources of data to correlate the number of chairs per office to the revenue range of dental offices. EPA averaged the correlation of these two studies. 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	13,694	10,700	12,197
3 chairs	47,698	27,821	25,835
4 chairs		32,102	27,976
5 chairs	29,388	15,694	15,194
6 chairs		9,399	12,047
7+ chairs	19,079	14,143	16,611
Total	109,859	109,859	109,859

Dentistry may also be performed at larger institutional dental service facilities (e.g., clinics or dental schools). These facilities are not included in the 2007 Economic Census data. EPA estimates 130 dental institutional facilities exist nationwide. EPA recognizes that large facilities also may exist at installations operated by the Federal Government, specifically the Department of Defense. While EPA intends such facilities would be subject to today's proposed rule, EPA does not have information to estimate the number of such facilities.

EPA currently lacks a central database on reported discharges from dental offices/clinics. Often, EPA looks to information in the Toxic Release Inventory (TRI) and Discharge Monitoring Report (DMR) databases to gather information on industrial discharges. However, no dental offices/clinics (NAICS Code 621210) are required to report releases to TRI. EPA identified only five dental offices that have National Pollutant Discharge Elimination System (NPDES) permit information. All dental offices were classified as minor dischargers. EPA has not found any DMR data indicating that any significant number of dental offices discharge directly to waters of the U.S. Therefore, EPA is not proposing effluent limits for direct dischargers.[6]

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

[6] EPA recognizes that some dental facilities may discharge to a septic system. This proposed rule does not apply to such discharges.

X. Summary of Data Collection

In developing this proposed rule, EPA primarily used data previously collected for its Health Services Detailed Study including information submitted in public comments on the study. EPA also collected information and data through outreach to a number of stakeholders. The following describes EPA's outreach and additional data sources for this proposed rule.

A. Health Services Industry Detailed Study on Dental Amalgam

In 2008, EPA published its Health Services Industry Detailed Study on Dental Amalgam. In the study, EPA compiled information on mercury discharges from dental offices, BMPs, and amalgam separators. For amalgam separators, EPA examined the frequency with which they were used; their effectiveness in reducing discharges to POTWs; and the capital and annual costs associated with their installation and operation. EPA also conducted a POTW pass-through analysis on mercury for the industry. This proposed rule relies heavily on data collected for the study (including information submitted in public comments on the study).

B. Environmental Council of the States (ECOS)

EPA participated in several meetings with the Quicksilver Caucus (QSC) of ECOS. From QSC, EPA collected information on implementing mandatory amalgam separator programs at the state level, mandatory program language, and information on compliance reporting and monitoring. QSC also provided EPA with information on efficiency standards for amalgam separators. See DCN DA00158.

C. Environmental Organizations

EPA met with a coalition of environmental organizations, led by the Environmental Law and Policy Center and the Natural Resources Defense Council. Meetings between EPA and the coalition of environmental organizations focused on identifying impacts of discharges of dental amalgam to the environment. In Spring 2011, the coalition submitted a letter listing its suggested BMPs for this proposed rule. See DCN DA00136.

D. ADA

EPA met with the ADA in 2010 and 2011. ADA submitted data to EPA on its principles for addressing mercury discharges from dentists, the proportions of specialties in the industry, the geographic distribution of dentists, financial characteristics of the industry, and operating characteristics of the industry. See DCN DA00137.

E. NACWA

EPA met with NACWA in 2010 and 2011 to discuss the impact of pretreatment standards on POTWs. NACWA provided EPA information on its members' experiences with handling mercury pollution from dental facilities, implementing pretreatment programs for dental facilities, and its experiences implementing pretreatment standards for industries with similar characteristics to the dental sector. NACWA also provided EPA with information on the burden to permitting authorities that would be associated with implementing a dental amalgam pretreatment standard under the existing requirements in 40 CFR part 403. See DCN DA00144.

F. Amalgam Separator Manufacturers

EPA met with, or participated in calls with, representatives of multiple amalgam separator manufacturers. The purpose of the meetings was to understand how amalgam separators work, limitations of the technology, manufacturers' distribution methods, installation requirements, capital and operation and maintenance costs, operation and maintenance requirements, effectiveness, equipment lifetime, amalgam disposal or recycling practices, manufacturing capacity, and installation trends.

G. Air Force Study

In anticipation of this proposed rule, the United States Air Force's Dental Evaluation and Consultation Service compiled a synopsis of commonly used amalgam separator systems. The synopsis describes whether or not the separator is International Organization for Standardization (ISO) 11143 certified, the installation requirements, the design capacity, maintenance requirements for each model, the availability of recycling services by the manufacturer, size, price, and warranty details. EPA incorporated these data into the technology cost analysis. The synopsis can be found in the TEDD for this proposed rule.

XI. Wastewater Characteristics, Dental Office Configurations, and Technology Options

A. Wastewater Sources and Wastewater Characteristics

Dental amalgam consists of approximately 49% 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% silver, 9% tin, 6% copper, 1% zinc and small amounts of indium and palladium (DCN DA00131). Sources of mercury 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 chair-side drain, or suctioned out of the patient's mouth. In addition to filling new cavities, dentists also remove old cavity restorations that are worn or damaged. Removed restorations also may be rinsed into the chair-side drain or suctioned out of the patient's mouth. The second category of mercury discharges occur 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 mercury from dental amalgam to be discharged.

B. Dental Office Configurations

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% of dental amalgam particles from the wastewater stream (DCN DA00163). Offices with multiple chairs typically share the vacuum lines between chairs. Accordingly, this limits the locations for installation of control and treatment technologies. Controls may be installed: At or near each individual chair; within the vacuum system piping; at a central location upstream of the vacuum pump; or at the exit of the air/water separator portion of the vacuum system. Physical office and building configurations may pose additional considerations, such as space limitations, electrical power accessibility, and existing sewer connections. In the case of very large offices, clinics, and medical buildings, it may be possible to combine waste flows between offices to share or reduce costs.

C. Control and Treatment Technologies and Best Management Practices

As described previously, one source of the discharge of mercury from dental amalgam occurs when dental amalgam enters the chair-side drain, or is suctioned from the patient's mouth. The wastewater then travels through the dental facility's vacuum system. EPA

identified two major technologies that intercept dental amalgam at this point, before it is discharged from the dental office and flows to the POTW: Separators and ion exchange. EPA also identified several BMPs which, when employed along with the use of the technologies discussed below, further reduce the discharge of dental amalgam from activities not directly related to the placement or removal of dental amalgam.

1. Amalgam Separators

An amalgam separator is a device designed to remove solids from dental office wastewater. The amalgam separator is placed at some point in the vacuum line, before the vacuum line intersects with plumbing in other parts of the building, and separates solids from wastewater. Most separator designs rely on the force of the dental facility's vacuum to draw wastewater into the separator. However, the separation of solids from the wastewater and the exit of the wastewater from the separator will vary by design of the separator.

Practically all amalgam separators on the market today use sedimentation processes. The high specific gravity of amalgam allows effective separation of amalgam from suspension in wastewater. Baffles or tanks can reduce the speed of the wastewater flow, allowing more amalgam particles to settle out. After the solids settle, the wastewater is either pumped out, decanted during servicing, or is pulled through the separator. Sedimentation-based separators are often used over other separation technologies for their operational simplicity.

Some amalgam separators may combine filtration with separation. Different types of filtration units can be employed to remove additional amalgam particles. The amalgam separator may also be designed to operate horizontally where wastewater is drawn into one side of the separator, filtered, and then exits the opposite side of the separator. This type of separator is designed to be completely replaced once it reaches its design solids holding capacity. In addition to combined separation and filtration units, EPA is aware of at least one type of separator that utilizes centrifugation. A centrifuge-based separator spins the water so that the heavier amalgam particles are forced to the sides of the separator.

A few amalgam separators combine sedimentation (with or without filtration) with ion exchange in the same unit. This type of separator additionally includes a chelating agent or proprietary resin. This type of separator often requires special cleaning or additives to maintain efficiency.

The typical amalgam separator will operate in one of two ways. A two-chambered separator is a design consisting of a base permanently plumbed into the vacuum line, and a replaceable filtration cartridge. The removable cartridge usually attaches to the bottom of the permanent base. As wastewater enters the separator from the top of the unit, gravity separates the wastewater from the air pulling it through the vacuum. Air from the vacuum continues through the system by exiting a bypass at or near the top of the base chamber. Wastewater then falls through the base of the separator and enters the filtration cartridge. As additional wastewater enters the separator, the filtration cartridge will fill to capacity, and wastewater will begin to collect at the bottom of the base chamber. Gravity forces wastewater in the separator through a filtration device and out of the separator through a decanting tube on the side of the separator. The wastewater, less the solids retained by the separator, then continues through the vacuum system and is eventually discharged from the dental office and to the sanitary sewer and the POTW. The second common separator design consists of a single chamber that requires wastewater to travel through a filtration medium before it is drawn out of the separator. These separators may be oriented vertically so that wastewater enters the top of the unit, remains in the separator for some time, and allows solids to settle. For either design, when the filtration cartridge or the separator itself reaches the designed solids retention capacity, it must be replaced. Manufacturers can include replacement schedules and capacity levels for amalgam separators.

The vast majority of amalgam separators on the market today have been evaluated for their ability to meet the International Organization for Standardization Standard for Dental Amalgam Separators (*http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42288*). This voluntary standard setting organization established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam mercury using specified test procedures in a laboratory setting. It also includes requirements for instructions for use and operation and maintenance. In order to obtain the ISO certification, a separator must achieve 95% removal or greater of total mercury. Based on EPA's evaluation of a range of amalgam separators as described above that meet the ISO standard and that are currently on the market, certified separators obtain a median of 99.0% total mercury removal efficiency (see Section 7 of the TEDD). 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% (DCN DA00008).

EPA is proposing to include certain operation, maintenance, and inspection activities that have the greatest impact on the ability of an amalgam separator to achieve its performance as certified. Once the separator reaches solids retention capacity, vacuum suction will begin to diminish or, more commonly, the separator will enter bypass mode. Wastewater running through a separator in bypass mode flows through the separator without being filtered, rendering the separator ineffective. Because many separators can enter bypass mode without any noticeable effect on vacuum suction, it would be important that the unit be checked periodically, and if necessary, serviced.[7]

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. Amalgam separator manufacturer instructions should be followed for servicing amalgam separators and for handling separator waste. Some amalgam separator manufacturers also offer waste management services. Examples of services provided include ensuring that waste collected by the separator is handled according to state and local requirements, and providing necessary compliance documentation for the facility's recordkeeping requirements. In the event that these services are not employed, the facility should dispose of amalgam waste in accordance with state and local requirements.

Most amalgam separators are compatible with both wet and dry vacuum systems, and with both large and small dental offices.[8] As explained in Section VIII, currently at least 12 states and 19 localities have implemented mandatory programs to reduce dental mercury discharges. All of these programs require the use of

[7] There may be separators on the market that do not notify users when they are in bypass mode or otherwise require servicing. These separators would not meet ISO certification standards.

[8] This does not mean all types of separators are compatible at a given dental office. For example, an amalgam separator that relies on filtration technology may not be compatible with a dry vacuum system in place.

amalgam separators. Further, many dental offices in states or localities without mandatory programs have voluntarily installed dental amalgam separators, and the ADA recommends their use as part of its ''Best Management Practices for Amalgam Waste'' (2007). As described in Section VIII, EPA estimates that 40% of dental offices currently employ amalgam separators.

2. Polishing To Remove Dissolved Mercury From Wastewater

Mercury in dental amalgam is present in both the suspended and dissolved form. The vast majority (>99.6%) is suspended (DCN DA00018). An additional process sometimes referred to as ''polishing'' uses ion exchange to remove dissolved mercury. In contrast to amalgam separators that contain an ion exchange component in the same unit, as discussed in the previous section, ''polishing'' ion exchange refers to a separate wastewater treatment system added after the amalgam separator for the purpose of removing dissolved mercury.

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. Ion exchange does not rely on physical settling of particles, and can remove very small amalgam and ionic mercury particles. This technology may be preferable over sedimentation (with or without filtration) alone because dissolved mercury is removed by this process. For example, ion exchange might be useful in municipalities that have concentration limits on mercury (McManus, 2003). EPA is not aware of any state regulations that require ion exchange.

For ion exchange to be most effective, the incoming wastewater to be treated must first have the solids removed. Then the wastewater needs to be oxidized 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. As a result, EPA concludes this sequential polishing approach, in which amalgam separators and ion exchange are separate units, is more effective than the single units described above that combine sedimentation and ion exchange. Dental offices needing to employ polishing would likely need to add a separate ion exchange unit following the amalgam separator to remove additional mercury from the waste stream.

As explained above, ISO certification testing is based on an evaluation of the removal of total mercury in a laboratory setting and does not differentiate removal for the suspended and dissolved forms.[9] In order to better understand the reductions in dissolved mercury that can be achieved with the addition of ion exchange as polishing, EPA reviewed available data on the performance from actual installations of ion exchange units in addition to amalgam separators in dental offices. EPA found the use of polishing is limited to just a handful of dental offices. EPA identified only one study of polishing systems, and has not identified any further data pertaining to the performance of polishing. This one study evaluated the additional efficacy associated with polishing at two dental facilities in response to sanitation district concerns over mercury discharges. In both cases, the polishing systems were installed after the amalgam separators but prior to discharge into the treatment plant's collection system. While a reduction was observed in the final effluent mercury after the polishing system was installed, preliminary EPA Region 8 audits showed the total additional mercury reductions were typically on the order of 0.5% (DCN DA00164). This is not surprising since, as indicated above, dissolved mercury contributes such a small portion to the total amount of mercury in dental amalgam. It is unclear whether any solid mercury was converted to dissolved mercury, and additional monitoring data are not yet available.

The capital costs of the polishing system, as a stand-alone system, are approximately four times that of the amalgam separator; the costs for chemical use, regenerating the resin, filter replacement, and other operational costs were not reported. Further, EPA is uncertain whether typical dental buildings have adequate space to install the holding tanks needed to oxidize the waste before treatment, as well as space for the polishing equipment itself.

D. Best Management Practices

EPA considered what BMPs reflect the best available technology economically achievable or best available demonstrated control technology—the standards applicable to existing and new sources subject to categorical pretreatment standards. After this review, EPA proposes to include certain operation, maintenance, and inspection practices as part of the technology basis for this proposed rule. These practices have the greatest impact on the ability of an amalgam separator to achieve its performance as certified.

EPA also proposes to require two BMPs to control mercury discharges that would not be captured by an amalgam separator. Bleach and other corrosive cleaners can solubilize bound mercury. If corrosive cleaners are used to clean vacuum lines that lead to an amalgam separator, the line cleaners may solubilize any mercury that the separator has captured, leading to increased mercury discharges. Therefore, EPA proposes to require line cleaners that do not contain bleach, and are of neutral pH.

Flushing scrap amalgam (contact and non-contact), including dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, or collection devices into drains that do not have a solids collecting device presents additional opportunities for mercury to be discharged from the dental office. Therefore, EPA proposes to include a BMP that prohibits flushing scrap dental amalgam into any drain that is not connected to an amalgam separator.

XII. Scope/Applicability

As mentioned in the previous section, EPA has not identified dental offices/clinics discharging directly to waters of the U.S. Because EPA has very limited information on any direct discharge of dental amalgam, EPA is not proposing effluent limitations guidelines and new source performance standards for direct dischargers at this time.

As such, EPA is proposing to apply this rule to wastewater discharges to POTWs from offices where the practice of dentistry is performed, including institutions, permanent or temporary offices, clinics, mobile units, home offices, and facilities, and including dental facilities owned and operated by Federal, state, or local governments. EPA is not proposing to include wastewater discharges from dental facilities 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 do not engage in the practice of restorations or removals, and are not expected to have any discharges of dental amalgam.

XIII. Subcategorization

In developing effluent limitations guidelines and pretreatment standards, EPA may divide an industry category into groupings called ''subcategories'' to

[9] In some cases, the ISO testing results include ranges of dissolved mercury in the effluent.

provide a method for addressing variations among products, processes, and other factors, which result in distinctly different effluent characteristics. *See Texas Oil & Gas Ass'n.* v. *U.S. EPA,* 161 F.3d 923, 939–40 (5th Cir. 1998). Regulation of a category by subcategories provides that each subcategory has a uniform set of effluent limitations or pretreatment standards that take into account technological achievability, economic impacts, and non-water quality environmental impacts unique to that subcategory. In some cases, effluent limitations or pretreatment standards within a subcategory may be different based on consideration of these same factors, which are identified in CWA section 304(b)(2)(B). The CWA requires EPA, in developing effluent guidelines and pretreatment standards, to consider a number of different factors, which are also relevant for subcategorization. The CWA also authorizes EPA to take into account other factors that the Administrator deems appropriate.

In developing the proposed rule, EPA considered whether subcategorizing the dental industry was warranted. EPA evaluated a number of factors and potential subcategorization approaches, including the size of dental office, specialty practices, and unusual configurations that may be found at very large offices such as clinics and universities. EPA proposes that establishing formal subcategories is not appropriate for the Dental Amalgam category for three reasons. First, the proposed rule is structured to set standards only for those facilities that discharge dental amalgam. Second, the requirements do not include a size threshold because the technology is readily scaled to the size of the dental office. Finally, those states and localities that already have regulatory programs for controlling discharges of dental amalgam have been largely successful without subcategorization.

XIV. Proposed Regulation

A. PSES Options Selection

Section XI discussed the technologies identified to control amalgam discharges from dental offices. EPA identified two basic technologies, amalgam separators and polishing. EPA determined separators plus polishing is not ''available'' as that term is used in the CCWA.

EPA identified one technology that is available and demonstrated—amalgam separators. EPA further identified BMPs that would ensure the effectiveness of the amalgam separator technology and would reduce discharges of dental amalgam not captured by an amalgam separator. Therefore, EPA developed a regulatory option based on proper operation and maintenance of amalgam separators that achieve a 99.0% reduction of total mercury from amalgam process wastewater with BMPs. Compliance with the numeric pretreatment standard for new and existing sources could be met by installation and proper operation and maintenance of an amalgam separator certified to meet at least 99.0% reduction of total mercury according to the 2008 ISO 11143 standard. Compliance with two additional BMPs—not flushing scrap amalgam down the drain and cleaning of chair side traps with non-bleach, non-chlorine cleaners—are necessary to prevent mercury discharges that would bypass the separator. EPA finds that the proposed technology basis is ''available'' as that term is used in the CWA because it is readily available and feasible for all dental offices. ADA recommends its dentists use the technology on which this rule is based (i.e., amalgam separators and BMPs). Further, EPA estimates that 40% of dental offices currently use amalgam separators on a voluntary basis or are in states with state or local laws requiring the use of amalgam separators. 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 $700 [10] per office. EPA's economic analysis analyzes these costs in relation to the overall income of the regulated entities and shows that this proposed rule is economically achievable (see Section XVI). Finally, EPA also examined the non-water quality environmental impacts of the proposed rule and found them to be acceptable. See Section XX, ''Non Water Quality Environmental Impacts.''

EPA is not proposing to establish pretreatment standards based on technologies that remove dissolved mercury, or polishing. None of the states with mandated requirements to reduce dental mercury discharges requires polishing. EPA also lacks adequate performance data to truly assess the efficacy of polishing or its availability of ion exchange for nationwide use. EPA's current information suggests that polishing only achieves incremental removals over the BAT selected technology of less than one half percent of total mercury. 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 the two technologies. EPA estimates that the capital costs of amalgam separators and polishing are at least four times that of amalgam separators alone (see DCN DA00122). Finally, EPA is uncertain whether existing dental offices have adequate space to install polishing controls. These factors led EPA to find that polishing is not ''available'' as that term is used in the CWA. As a result, EPA did not select amalgam separators followed by polishing as the technology basis for this proposed rule. EPA solicits data on the costs, performance, affordability, and availability of polishing in combination with amalgam separators.

B. Pollutants of Concern and Pass Through

Of the dental amalgam constituents, mercury is of greatest concern to human health because it is a persistent, bioaccumulative, toxic chemical and can bioaccumulate three to ten times across each trophic level of the food chain. Mercury from dental amalgam makes its way into the environment when it is discharged from the dental facility to a POTW, where it settles into sewage sludge, or is discharged to surface waters. Once discharged, certain microorganisms change mercury into methylmercury, a form of mercury that can be absorbed by fish, shellfish and animals that eat fish.

EPA finds that the technologies considered for control of amalgam solids will be similarly effective on other metals contained in dental amalgam because these metals are in a solids form, and the separation technology is designed to remove solids. Therefore any controls established for the reduction of mercury discharges will similarly reduce the discharge of other metals contained in amalgam. As such, EPA focused its consideration of regulated pollutants on mercury.

C. POTW Pass Through Analysis

To establish pretreatment standards, EPA examines whether the pollutants discharged by the industry ''pass through'' a POTW to waters of the U.S. or interfere with the POTW operation or sludge disposal practices. EPA's consideration of pass through for national technology based categorical pretreatment standards differs from that described in Section VIII for general pretreatment standards. For categorical pretreatment standards, EPA's approach for pass through satisfies two competing objectives set by Congress: (1) That standards for indirect dischargers be

[10] This estimate is based on the average annualized cost for dentists that do not currently have an amalgam separator. See DCN DA00145.

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.

Generally, in determining whether pollutants pass through a POTW when considering the establishment of categorical pretreatment standards, EPA compares the percentage of the pollutant removed by typical POTWs achieving secondary treatment with the percentage of the pollutant removed by facilities meeting BAT effluent limitations. A pollutant is deemed to pass through a POTW when the average percentage removed by a typical POTW is less than the percentage removed by direct dischargers complying with BPT [11]/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 proposed rulemaking, where only pretreatment standards are being developed, EPA compared the POTW removals with removals achieved by indirect dischargers using the candidate 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). The 50 POTW study presents data on the performance of 50 POTWs achieving secondary treatment in removing toxic pollutants. Results of this study demonstrate POTWs remove 90% of total mercury found in wastewater. EPA has data from targeted studies performed by NACWA and ADA that indicate a POTW can remove 95% of total mercury. However, these studies reflect the performance of best performing POTWs, as opposed to the 50 POTW Study which reflects nationwide POTWs. Consequently, for this proposal, EPA maintains a POTW percent removal rate of 90% for its nationwide pass-through analysis. In comparison, indirect dischargers using this proposed technology will remove 99.0% or more total mercury prior to discharge. Therefore, EPA concludes mercury passes through [12] and is today proposing requirements to control its discharge.

D. Requirements

This proposed rule would establish a pretreatment standard that would require removal of at least 99.0% of total mercury from amalgam discharges and BMPs. One way affected dental offices would be able to meet the standard would be to use, and properly operate and maintain, a dental amalgam separator certified to achieve at least 99.0% reduction of total mercury according to the 2008 ISO 11143 standard, to perform certain BMPs, and to certify to this effect. Another way affected dental offices would be able to meet the standard would be to certify that they do not install or remove amalgam except in limited emergency circumstances. Dentists that certify that they do not install or remove amalgam will be exempt from any further requirements of the proposed rule.

While the proposed rule does not require the use of an amalgam separator to meet the numeric standard, EPA expects that most, if not all dentists that place or remove amalgam would use this widely available technology to comply with the proposed numeric standard. EPA expects dentists will choose to install and operate an amalgam separator because of the nature of dental offices, the variability of the flows and resulting waste streams, and the difficulty in obtaining a sample that represents only dental amalgam discharges. Moreover, amalgam separators are an easy to use, low cost technology. Dental offices that elect to not use an amalgam separator must meet the proposed numeric limit and would be subject to the oversight and compliance requirements for indirect discharges subject to national pretreatment requirements.

In selecting an amalgam separator that meets the requirements of today's proposed pretreatment standards, dentists would verify that the amalgam separator is compliant with the 2008 ISO 11143 standard and meets the design specifications of the proposed regulation for their configuration. Once selected and installed, EPA expects dentists will operate and maintain the separator following all manufacturer's instructions and conduct inspections at least monthly to ensure all features are functional.

This proposal would subject all dentists (except those specialists as described in Section XII) to categorical pretreatment requirements. EPA recognizes that some dentists covered by this proposal do not apply or remove dental amalgam except possibly in limited emergency circumstances. However, EPA, in consultation with pretreatment authorities, has been unable to identify a publically available source of information that differentiates dental offices on the basis of whether or not dental amalgam may reasonably be expected to be present. As such, this proposed rule would apply to such dischargers and require them to report baseline information, but it would also allow them to certify (at any time) that they do not and will not install or remove amalgam (not including infrequent emergency treatment as discussed below). This would fulfill their obligations under this proposed rule. If they subsequently elect to install or remove amalgam, they would then need to comply with the proposed numeric standard (e.g., proper operation and maintenance of an amalgam separator) and with the BMPs in this proposed rule.[13]

EPA does not want to penalize existing dental offices or institutional dental facilities that have already installed amalgam separators either voluntarily or to comply with state or local requirements. EPA recognizes that these offices may currently have amalgam separators in place that are certified to a removal rate slightly less than this proposed standard. For example, some states require dental offices to employ amalgam separators that are certified to remove 95% total mercury. EPA does not propose a rule that would require existing separators that still have a remaining useful life to be retrofitted with new separators, both because of the additional costs incurred by dental facilities that moved ahead of EPA's proposed requirements to install a treatment technology and because of the additional solid waste that would be generated by disposal of the existing separators. Therefore, EPA is proposing that, as long as they continue to properly operate and maintain existing separators, comply with BMPs, and comply with recordkeeping requirements, these facilities would be considered in compliance with the numeric standard until ten years from the effective date of the final rule. EPA selected ten years because it appears to be a conservative estimate of the useful life of the existing equipment. However, if prior to that time, the currently installed separator needs to be replaced, these facilities would need to install and

[11] Best Practicable Control Technology Currently Available.

[12] For all the metals contained in dental amalgam, EPA's record demonstrates that these pollutants would similarly pass through as defined above. See the Pollutant Reduction Estimates section of the TEDD for POTW removal estimates for the other metals.

[13] EPA recognizes that dentists, infrequently, may remove amalgam in the course of emergency treatment. EPA does not intend for discharges of dental amalgam, related to only these infrequent emergency treatments, to preclude such dentists from certifying.

operate an amalgam separator that meets a removal efficiency of 99.0%.

EPA requests comment on this proposed regulatory scheme. In particular, EPA seeks comment on its approach for addressing offices where no dental amalgam is placed or removed except in limited emergency circumstances, and its approach for offices that have already installed an amalgam separator.

E. PSNS Option Selection

As previously noted, under section 307(c) of the CWA, new sources of pollutants into POTWs must comply with standards which 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. EPA proposes PSNS that would control the same pollutants using the same technologies proposed for control by PSES. The technologies used to control pollutants at existing offices, amalgam separators and BMPs, are fully applicable to new offices. New dental offices can incorporate amalgam separators into the design and installation of their vacuum system. Furthermore, EPA has not identified any technologies that are demonstrated for new sources that are more effective than those identified for existing sources. Finally, EPA determined that the proposed PSNS present no barrier to entry. EPA has found that overall impacts from the proposed standards on new sources would not be any more severe than those on existing sources, since the costs faced by new sources generally will be the same as or less than those faced by existing sources. Therefore, EPA proposes to establish NSPS that are the same as those proposed for PSES.

EPA does not propose to establish more stringent requirements for new sources based on technologies that remove dissolved mercury (i.e., polishing) for the same reasons stated above for existing standards.

XV. Technology Costs

This section summarizes EPA's approach for estimating compliance costs, while the TEDD provides detailed information on the methodology. EPA's cost methodology assumes dental offices would use the required BMPs in combination with 2008 ISO 11143 amalgam separators on the market today to comply. See DCN DA00138. EPA categorized all of the costs as either capital costs [14] (one-time costs associated with planning or installation of technologies), as operation and maintenance (O&M) costs (costs that occur on a regular ongoing basis such as inspection or cleaning of the unit or annual purchases of amalgam cartridges), or as reporting costs. All final cost estimates are expressed in terms of 2010 dollars.

EPA estimated compliance costs associated with this proposal using data collected through EPA's Health Services Industry Detailed Study (August 2008) [EPA–821–R–08–014], a review of the literature, and information supplied by vendors. EPA's cost estimates represent the incremental costs for a dental office to comply with this proposed rule. For costing purposes, EPA differentiated dental offices by those that already use amalgam separators and those that do not.

EPA recognizes that some fraction of dental offices subject to this proposed rule may not place or remove amalgam and proposes to allow them to submit a one-time baseline monitoring report. Such dental offices would be exempt from this rule so long as they do not place or remove amalgam. Should the status of the dental office change, the certification would no longer be valid. For example, if a dental office so certifies and is sold, the new owner must similarly so certify or would need to comply with the rule. See § 441.10. EPA estimates the costs associated with this one-time only certification to be $22.

In general, one approach that EPA takes to estimate compliance costs is to use facility-specific data to determine what requirements apply to a given facility and whether that facility would already meet the proposed requirements. This approach requires facility specific technical and financial data. In this case, EPA would need such data for approximately 110,000 dental offices estimated to be subject to this rule. Such data are not available. An alternative approach often used by EPA is to develop a series of model facilities that exhibit the typical characteristics of the affected facilities and calculate costs for each model facility. EPA can then determine how many of the affected facilities are represented nationally by each model facility to represent the full universe of affected facilities.

A. Methodology for Developing Model Dental Office Costs

EPA used the model approach to estimate costs for facilities that place or remove amalgam for this proposal. The model facility approach used in this effort involved calculating compliance costs for each of the size classes of dental offices described in Section IX of this preamble. In other words, EPA developed compliance costs for six models 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, and 7+ chairs (average of 10 chairs). In addition to each of the size class models, EPA developed a model facility to represent very large offices such as clinics and universities. This is discussed separately in Section XV. B., below.

EPA developed two sets of costs for each model: one for facilities that do not use an amalgam separator and one for facilities that do. For those that do not use an amalgam separator, EPA estimated capital costs and operation and maintenance costs. Capital costs include purchase of the separator and installation. Recurring costs include replacement of the cartridge, and operation and maintenance costs. A summary of costs for dental offices that do not currently use amalgam separators may be found in Tables XV–1 and XV–2.

TABLE XV–1—SUMMARY OF ONE TIME MODEL FACILITY COSTS ($2010) 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 [15]	6	7+
Separator Purchase	$502	$599	$1,058	$1,531

[14] See Section XVI and the Economic Section of the Technical Development Document for information on how EPA annualized costs.

TABLE XV–1—SUMMARY OF ONE TIME MODEL FACILITY COSTS ($2010) FOR DENTAL OFFICES THAT DO NOT CURRENTLY USE AMALGAM SEPARATORS—Continued

Cost element	Number of chairs in the model dental office			
	1 or 2	3, 4, or 5 [15]	6	7+
Installation	250	250	250	250

TABLE XV–2—SUMMARY OF ONE TIME MODEL FACILITY COSTS ($2010) 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 [16]	6	7+
Replacement Parts	$195	$219	$430	$647
O&M Including Recycling	216	216	216	216

For those facilities that already have an amalgam separator, EPA calculated costs for certain additional recurring operation and maintenance associated with the amalgam separator compliance option in this proposal. Recurring costs include replacement of the cartridge and operation and maintenance costs. A summary of these costs may be found in Table XV–3. This is a conservative approach to costing, however, because some of these facilities would presumably continue to operate and maintain the separators that they have already chosen or been required to install.

TABLE XV–3—SUMMARY OF ANNUAL MODEL FACILITY COSTS ($2010) 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 [17]	6	7+
Replacement Parts	$98	$110	$215	$324
O&M including recycling	116	116	116	116

In assessing the long term costs of rule compliance for these model facilities (those with and without existing separators), EPA estimated that amalgam separators would have a service life of 10 years, at which time the amalgam separators would need to be replaced. For the purposes of cost estimates for this proposal, EPA assumed that all offices regardless of the original technology in-place would incur the full cost of purchasing amalgam separators at the time of reinstallation. However, because various modifications needed by the office for initial amalgam separator installation would have already been completed, EPA has projected that amalgam separators replaced beyond year 10 would be installed at one-half of the cost of the original installation. For example, EPA assumed plumbing modifications for initial installation would cost $250 per office, but that replaced equipment would cost $125 to install. EPA assumed that dental offices would continue to incur recurring expenses such as O&M in the same way as described for the initial installation.

Finally, all dental offices subject to this proposed rule will also have reporting requirements and BMP requirements. EPA also included reporting costs for one-time preparation of a baseline report and initial compliance report and recurring costs associated with preparation of an annual certification statement. Section XI describes the BMPs in this proposal. EPA projects that there will be no incremental costs associated with these BMPs, because 1) costs for non-oxidizing, pH neutral line cleaners are roughly equivalent to other line cleaners; and 2) dentists will not incur additional costs by changing the location for flushing scrap amalgam.

[15] 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.

[16] 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.

[17] 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.

B. Methodology for Developing Costs for Institutional Facilities

Institutional dental service facilities (e.g., clinics or dental schools), have a larger number of chairs than the typical dental office. For these institutional dental facilities, EPA developed a costing methodology based on the methodology for offices described above. For purposes of costs, EPA assumed the average institutional facility has 15 chairs. In the methodology described previously, the model practice with the largest number of chairs for which EPA developed cost information is the 7+ chair model with an average of 10 chairs. Scaling the information on costs for the 10 chair model facility to a 15 chair operation using a straight ratio yields costs at these institutional facilities at 1.5 times the costs estimated for the largest chair range shown in Table XV–1 and Table XV–2. These costs are likely overstated as they do not reflect opportunities the largest offices may have to share costs,[18] and they do not assume any economies of scale. EPA solicits comment and data regarding EPA's analysis of clinics and institutional facilities.

XVI. Economic Impact Analysis

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

A. Social Cost Estimates

As described earlier in Section XIV of this preamble, EPA proposes PSES and PSNS based on a widely available technology, amalgam separator, and employment of BMPs. Section XV provides a detailed explanation of how EPA estimated compliance costs for model dental offices. As described there, EPA developed compliance costs for six models 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, and 7+ chairs (average of 10 chairs). In addition to each of the size class models, EPA developed a model facility to represent institutional facilities such as clinics and universities.

For each model facility, EPA estimated compliance costs for dental offices that currently use a separator, those that do not have a separator in place, and those that certify that they do not place or remove amalgam. For those that do not currently use a separator, EPA estimated costs as either capital costs (one-time costs associated with planning or installation of technologies), as O&M costs (costs that occur on a regular ongoing basis such as inspection or cleaning of the unit, annual purchases of amalgam cartridges, and recycling), and as reporting costs. For those that use a separator (approximately 40% of dental offices as reported in Section VIII), EPA estimated O&M costs and reporting costs only. As applicable, EPA annualized the capital costs over a 20-year period at a discount rate of 3%[19] and summed these costs with the O&M and reporting costs to determine an annual compliance cost estimate for each model facility. In order to develop a national estimate of social costs[20] based on these model facilities, EPA estimated the number of dental offices represented by each model facility. As explained in Section IX, EPA estimated the number of dental offices based on data from the 2007 Economic Census[21] describing the number of establishments in the Offices of Dentists NAICS (621210), and their annual revenue. Because reported establishments were described by their annual revenue and not number of chairs (the basis of model compliance costs), EPA used data from two surveys, a Colorado survey and an ADA survey, to correlate the estimated number of chairs per office to the revenue range of dental offices. Because EPA used two different data sources, results are presented as a range. Details of the relationship between chairs and revenue can be found in the TEDD.

To estimate nationwide social costs, EPA multiplied the estimated total annualized costs of rule compliance for each model facility 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). EPA also accounted for some dental offices that may not place or remove amalgam and assigned them costs only for a one-time baseline monitoring 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 facilities by multiplying the compliance cost for its model institutional facility by the number of estimated institutional facilities indicated in Section IX. Lastly, EPA estimated costs for control authorities for administering the Dental Amalgam Rule.[22] Details of this cost analysis can be found in the TEDD. See Table XVI–1 for EPA's estimate of nationwide annualized costs for each chair range represented by EPA's model facilities as well as EPA's estimate of total nationwide annualized costs for this proposed rule.

TABLE XVI–1—TOTAL ANNUALIZED SOCIAL COSTS BY NUMBER OF CHAIRS

[Millions of 2010 dollars]

Number of chairs	Total annualized costs by chair size [1]	
	Colorado survey	ADA Survey
1–2 chairs	$3.4	$4.4
3 chairs	9.5	16.3
4 chairs	11.0	
5 chairs	5.4	14.8
6 chairs	4.7	
7+ chairs	9.5	12.8
Large Dental Facilities	0.1	0.1

[18] 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.

[19] See the TEDD for the reported analyses using a 7% discount rate.

[20] 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.

[21] EPA adjusted the 2007 Economic Census revenue values to reflect 2010 dollars.

[22] As a point of clarification, for this proposal, social costs equal the sum of compliance costs and administrative costs.

TABLE XVI–1—TOTAL ANNUALIZED SOCIAL COSTS BY NUMBER OF CHAIRS—Continued

[Millions of 2010 dollars]

Number of chairs	Total annualized costs by chair size [1]	
	Colorado survey	ADA Survey
Cost to Control Authorities	0.9	0.9
Total Annualized Social Costs	44.5	49.4

[1] 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% discount rate was used for the analysis reported in this table, see the TEDD for the analysis with a 7% discount rate.

B. Economic Impact Methodologies

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

EPA did not conduct a traditional closure analysis for this proposed 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. However, such accounting measures are difficult to implement for businesses that are organized as sole proprietorships or partnerships, as is the case in the dental industry. Still, the 2007 Economic Census reports that approximately 700 offices of the approximately 110,000 total offices had revenue of less than $25,000 (2007 dollar basis). In reviewing the implied operating characteristics of these low revenue offices, EPA considered whether these offices should be excluded from the analyses on any of the following bases:

- These low revenue offices could be single-dentist and/or part-time businesses that provide services as a subcontractor on an independent fee-for-service basis, such as dental hygiene, in general service dental offices that are owned and operated by a larger dental practice. Because these establishments would not be the primary owner/operator of the dental offices in which they provide services, they would not directly incur the compliance costs of a Dental Amalgam Rule. If they incurred any of these costs, it would be on a limited fractional share basis, most likely in proportion to the total value of their services as a fraction of the total revenue in the office. On the other hand, if these operators offer their services in a competitive market, it may be that none of the compliance costs are shared by these subcontractors.
- Another possibility is these very low revenue offices could be non-profit groups which provide pay-as-you-can or free services to a low-income populations. In this case, these small businesses may be viable enterprises because they receive in-kind donations not counted as revenue, e.g., services of a practicing dentist.
- Alternatively, these low revenue offices may be non-viable as for-profit businesses, if they are attempting to operate as general service dental practices. This is based on EPA's assessment (see Ratio of Proposed Rule Capital Costs to Total Dental Office Capital Replacement Costs, below) that 1–2 chair offices would incur pre-rule capital replacement costs of approximately $23,500 per year. This cost represents all or a substantial fraction of annual revenue of the business in the below-$25,000 revenue range. Accordingly, these businesses may not be operating viably as for-profit general service dental offices.

As such, EPA could consider these offices to be the equivalent of baseline closures as traditionally accounted for in cost and economic impact analysis for effluent guidelines rulemakings. As a result 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. EPA solicits comment for additional information on these low revenue dental offices.

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 for ELGs when looking at impacts to small businesses. The cost-to-revenue analysis compares the total annualized compliance cost of each regulatory option with the revenue of the entities. It is also used 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. EPA apportioned all dental offices into Economic Census revenue ranges. Using the relationship between revenue and number-of-chairs previously developed, each revenue range was assigned to a number-of-chairs category which determined its annual costs. EPA looked at whether all, some, or none of the offices in each revenue range would exceed the 1% or 3% threshold (to signal the potential for significant impact), and summed across chair-size categories to assess impact to the industry. To incorporate the discussion of low revenue dental offices described in Section XVI.B above, this analysis is conducted twice: (1) Excluding dental offices that could represent baseline closures and (2) including all offices in the analysis.

2. Ratio of the Proposed 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 proposed rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting. EPA relied on data from Risk Management Association (RMA) [23] to estimate the average asset-to-sales ratio

[23] Risk Management Association reports financial statement information received from lending institutions, for businesses in a wide range of economic sectors, including Dental Offices. These data include a wide range of income statement and balance sheet information as well as financial and operating ratios.

in each number-of-chairs category for the dental office sector. This ratio was then applied to the revenue range/number-of-chairs categories to find an asset value for the minimum (reported as low in Table XVI–3) and maximum (reported as high in Table XVI–3) revenue values for that number-of-chairs category. EPA used these baseline assets by number-of-chairs category as the denominator for the ratio. Total proposed rule compliance costs, as described in Section XVI.B above, were assigned to each number-of-chairs category as the numerator for the ratio. To incorporate the discussion of low revenue dental offices described in Section XVI.B above, this analysis is conducted twice: (1) Excluding dental offices that could represent baseline closures, and (2) including all offices in the analysis. This analysis assumes a minimum revenue value of $5,000 for the lowest revenue range to prevent division by zero.

The RMA data contains the limitation that it may not be fully representative of all dental offices, because it only represents dental offices that are successful borrowers. It is possible that offices that are not financially healthy may be underrepresented in the RMA data. This would tend to understate EPA's finding of impacts.

3. Comparison of the Proposed 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 proposed rule to the estimated capital replacement costs for a dental office business (e.g., computer systems, chairs, x-ray machines, etc.). 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 proposed rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting. However, because EPA expects that annual dental office capital replacement would be smaller than total dental office capital assets, this ratio is likely to result in a higher value than the previous ratio. Because this ratio is based on a different data source, it provides an independent check that abstracts from the limitations of the RMA data.

EPA used data from *Safety Net Dental Clinic Manual,* prepared by the National Maternal & Child Oral Health Resource Center at Georgetown University (see DCN DA00143). This study examines data describing the equipment needs and costs for starting a dental practice for a range of different number-of-chairs including information on the life of the dental equipment. EPA then used these data to estimate 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. EPA used these replacement capital costs by number-of-chairs as the denominator for the ratio. Total proposed rule compliance costs, as described in Section XVI.B above, were assigned to each number-of-chairs as the numerator for the ratio.

Because the data are for starting a dental clinic instead of a dental practice, EPA is taking comment to solicit additional information on equipment needs and costs for starting a dental practice, including information on the life of the dental equipment. See the TEDD for details on this analysis.

C. Results of Impact Analysis

1. Cost-to-Revenue Analysis Results

Following the methodology outlined in XVI.B, EPA estimated the occurrence of annualized compliance costs exceeding the 1% and 3% of revenue thresholds for the proposed option twice: (1) Excluding dental offices that could represent baseline closures, and (2) including all offices in the analysis.

Table XVI–2 summarizes the results from this analysis. As shown there, under either scenario, over 99% of dentists would incur annualized compliance costs of less than 1% of revenue. With baseline set-asides excluded from the analysis, 507 offices (0.5% of offices using dental amalgam and exceeding the set-aside revenue threshold) are estimated to incur costs exceeding 1% of revenue; no offices are estimated to incur costs exceeding 3% of revenue. With baseline set-asides included in the analysis, 965 offices (0.9% of offices using dental amalgam) are estimated to incur costs exceeding 1% of revenue; 221 offices (0.2% of offices using dental amalgam) are estimated to incur costs exceeding 3% of revenue.

TABLE XVI–2—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	12,197	507	4.2	0	0.0
3 chairs	25,835	0	0.0	0	0.0
4 chairs	27,976	0	0.0	0	0.0
5 chairs	15,194	0	0.0	0	0.0
6 chairs	12,047	0	0.0	0	0.0
7+ chairs	16,611	0	0.0	0	0.0
Total	109,859	507	0.5	0	0.0
Including Baseline Set-Aside Offices in Analysis					
1–2 chairs	12,197	965	7.9	221	1.8
3 chairs	25,835	0	0.0	0	0.0
4 chairs	27,976	0	0.0	0	0.0
5 chairs	15,194	0	0.0	0	0.0
6 chairs	12,047	0	0.0	0	0.0
7+ chairs	16,611	0	0.0	0	0.0

TABLE XVI–2—COST-TO-REVENUE ANALYSIS IMPACT SUMMARY—Continued

Number of chairs	Total offices by chair size	Costs >1% Revenue		Costs >3% Revenue	
		Number	Percent	Number	Percent
Total	109,859	965	0.9	221	0.2

Source: EPA analysis.

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

Table XVI–3 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 0.5% to 1.0% for the no technology in-place case and 0% 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 0.6% to 1.2% for the no technology in-place case and 0% for the technology in-place case.

TABLE XVI–3—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 Establishments from Analysis				
1–2 chairs	0.1	0.1	2.7	1.3
3 chairs	0.0	0.0	0.8	0.5
4 chairs	0.0	0.0	0.5	0.3
5 chairs	0.0	0.0	0.3	0.2
6 chairs	0.0	0.0	0.3	0.2
7+ chairs	0.0	0.0	0.2	0.2
Weighted Average	0.0	0.0	0.7	0.4
Including Baseline Set-Aside Establishments in Analysis				
1–2 chairs	0.2	0.1	3.7	1.7
3 chairs	0.0	0.0	0.8	0.5
4 chairs	0.0	0.0	0.5	0.3
5 chairs	0.0	0.0	0.3	0.2
6 chairs	0.0	0.0	0.3	0.2
7+ chairs	0.0	0.0	0.2	0.2
Weighted Average	0.0	0.0	0.8	0.5

[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 proposed rule compliance costs, as described in Section XVI.B above, were assigned to each number-of-chairs category as the numerator for the ratio.

3. Ratio of the Proposed Rule's Capital Costs to Annual Dental Office Capital Replacement Costs Results

EPA compared the estimated total initial spending on the proposed rule's capital costs to the estimated capital replacement costs across all chair-sizes. The resulting values for the proposed option range from 2.9% to 3.5%, with a weighted average of 2.9% across all chair size ranges.

TABLE XVI–4—INITIAL SPENDING AS PERCENTAGE OF ESTIMATED ANNUAL DENTAL OFFICE CAPITAL REPLACEMENT COSTS [1]

Number of chairs	Percent
1–2 chairs	3.4
3 chairs	3.2
4 chairs	2.6
5 chairs	2.2

TABLE XVI–4—INITIAL SPENDING AS PERCENTAGE OF ESTIMATED ANNUAL DENTAL OFFICE CAPITAL REPLACEMENT COSTS [1]—Continued

Number of chairs	Percent
6 chairs	2.9
7 chairs	3.5
8 chairs	3.1
9 chairs	2.9
Weighted Average	2.9

Source: EPA Analysis.

[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. Total proposed rule compliance costs, as described in Section XVI.B, were assigned to each number-of-chairs as the numerator for the ratio.

D. Economic Achievability

The analyses performed above demonstrate the impact of this proposed rule on the dental office sector. In the cost-to-revenue analysis, EPA found that no more than 0.2% of offices, mostly in the lower revenue ranges, would potentially incur costs in excess of 3% of revenue. The two financial ratios reported in Tables XVI–3 and XVI–4 show that the proposed option would not cause dental offices to encounter difficulty in financing initial spending on capital costs of the proposed regulatory option. Based on the results of the three analyses above in combination, and EPA's inability at this time to conduct a traditional facility closure analysis, EPA has determined that the proposed pretreatment standard is economically achievable. EPA notes that, due to a lack of data, the economic

impact analyses did not include large institutional facilities. However, the results of the economic analyses performed on a range of office sizes indicate that this proposal is economically achievable at every level. Therefore, EPA projects the rule would similarly be achievable for large institutional facilities. EPA requests comment on this projection and data to perform economic achievability analyses.

E. Economic Impact for New Sources

EPA determined that this proposed pretreatment standard for new sources would not impose 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 facilities as described in Section XI) comprised 0.3% to 0.4% of the cost of starting a dental practice and, therefore, does not pose a barrier to entry.

TABLE XVI–5—INITIAL SPENDING AS PERCENTAGE OF ESTIMATED DENTAL OFFICE START-UP COSTS

Number of chairs	Percent
1–2 chairs	0.4
3 chairs	0.4
4 chairs	0.3
5 chairs	0.3
6 chairs	0.3
7 chairs	0.4
8 chairs	0.4
9 chairs	0.3
Weighted Average	0.3

Source: EPA Analysis.

XVII. Pollutant Reductions to POTWs and Surface Waters

Consistent with its costing methodology, EPA's pollutant reduction methodology assumes 2008 ISO 11143 amalgam separators on the market today with BMPs, the proposed technology basis, would be used to comply with this proposed rule. As was the case for costing, EPA does not have office specific discharge data for the approximately 110,000 dental offices potentially subject to this proposal. Instead, EPA has modeled the 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.[24] This is the same approach and data that EPA presented in its Health Services Industry Detailed Study (EPA 821–R–08–014). EPA did not receive comments on this part of the health study that would cause EPA to reconsider its approach, and, therefore, EPA did not change the overall methodology. The following sections describe the method in more detail.

A. Nationwide Estimate of Annual Mercury Discharges From Dental Offices

First, EPA estimated the amount of mercury potentially discharged nationwide through amalgam restorations. EPA's main source of the data underlying all of the estimates related to restorations is Vandeven and McGinnis, 2005 (DCN 00163). EPA estimates 71 million restorations occur at dental offices annually and that these restorations are performed with one amalgam capsule per restoration. Each amalgam capsule contains 450 mg of mercury and, on average, 75% of the capsule is used for the filling, with the remaining 25% remaining in the capsule. Therefore, 340 mg of mercury (75% of the capsule) are used per filling. Further, 9% of the 340 mg of mercury, or 31 mg, is discharged to the POTW as carvings and filings or other waste. Thus, EPA estimates a total of 2.4 tons of mercury nationwide[25] is discharged annually to POTWs from restorations.

Second, EPA modeled mercury discharges from amalgam removals. Similar to restorations, EPA's main source of the data underlying all of the estimates related to amalgam removals is Vandeven and McGinnis, 2005. Based on this information, EPA estimates approximately 97 million amalgam removals occur each year. An average of 300 mg mercury is removed from the filling. Ninety percent of the removed filling is assumed to be discharged to wastewater, and the other 10% is handled as dry waste and/or gray bagged. Thus, EPA estimates 29 tons of mercury are discharged to POTWs from removals each year.

Summing the total mercury discharged from restorations plus that associated with filling removals, 31.4 tons of mercury are potentially discharged annually to POTWs from dental offices. However, these calculations do not account for the amount of mercury removed at the dental office and prior to POTW discharge through existing chair side traps, vacuum pump filters, and/or amalgam separators as described below.

B. National Estimate of Annual Baseline Discharges of Mercury From Dental Offices to POTWs

As described in Section VIII, EPA estimates that 40% of dental offices currently operate dental amalgam separators. Thus, on a nationwide basis, approximately 65,000 dental offices currently do not have separators and 44,000 offices already have separators in place. Of the offices that do not currently have separators in place, EPA assumed that 20% do not install or remove amalgam, but EPA requests comment on this assumption. For the remainder, based on information in its record, EPA assumes all offices have chair side traps or a combination of chair side traps and vacuum filters that result in 68% and 78% collection of dental amalgam, respectively (Vandeven and McGinnis). After accounting for mercury reductions achieved through existing chair side traps, vacuum filters, and separators, as appropriate, EPA estimates the offices without separators that place or remove amalgam collectively discharge a total of 4.4 tons of mercury to POTWs per year. The offices with separators collectively discharge approximately 63 pounds of mercury to POTWs per year. Thus, EPA calculates the current nationwide annual baseline pounds of mercury discharged to POTWs from dental offices to be 4.4 tons mercury (out of a total of the 31.4 tons mercury originally generated). See Chapter 10 of the TEDD for more information.

C. National Estimate of Annual Baseline Discharges of Other Metals Contained in Amalgam From Dental Offices to POTWs

Amalgam is comprised of roughly 49% mercury, 35% is silver, 9% tin, 6% copper and 1% zinc[26] (DCN DA00131). As explained earlier in Section XI, EPA concludes the technology basis for this proposal would be equally effective in reducing discharges of silver, tin, copper, and zinc as it is in reducing mercury. EPA similarly assumes chair side traps and the combination of chair side traps and vacuum filters will result in 68% and 78% collection of these metals, respectively. Accordingly, after accounting for existing technologies at dental offices, EPA estimates that in

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

[25] 71 million restorations times 31 mg per restoration.

[26] It also contains small amounts of indium and palladium. EPA did not estimate discharges of these two pollutants.

addition to 4.4 tons of mercury, approximately 4.6 tons of these additional metals are discharged to POTWs annually for a total metal discharge to POTWs of 9 tons annually.

D. National Estimate of Annual Pollutant Reductions to POTWs Associated With This Proposal

1. Mercury

EPA estimates the 52,000 offices that install separators would obtain an additional 99.0% removal by amalgam separator (median removal efficiency of amalgam separators; see 7.1 of TEDD). This would result in reduction of total mercury discharges to POTWs by 4.3 tons. Because dissolved mercury accounts for much less than 1% of total mercury (DCN DA00018), and because amalgam separators are not effective in removing dissolved mercury, the dissolved mercury contribution and associated reduction in loads is assumed to be negligible. EPA solicits comment and data on this assumption.

2. Other Metals

As explained earlier in Section XI, EPA concludes the technology basis for this proposal 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 4.5 tons.

3. Total Reductions

EPA estimates this proposal would annually reduce mercury discharges by 4.3 tons and other metal discharges by 4.5 tons for a total annual reduction to POTWs of 8.8 tons.

E. National Estimate of Annual Pollutant Reductions to Surface Waters Associated With This Proposal

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 proposal, EPA estimates 4.4 tons of dental mercury is collectively discharged annually to POTWs. Based on the 50 POTW Study, EPA estimates POTWs remove 90% of the 4.4 tons mercury from the wastewater. Thus, POTWs collectively discharge 880 lbs of mercury from dental amalgam to surface waters annually. Under this proposed rule, 99.0% of the solid mercury currently discharged annually to POTWs will be removed prior to the POTW. The POTWs then further remove 90% of total mercury from the wastewater. This reduces the total amount of dental mercury discharged from POTWs nationwide to surface water to 14 lbs of mercury annually. In other words, discharges of mercury to waters of the U.S. are expected to be reduced by 860 pounds per year.[27] Similarly, EPA's 50 POTW Study data shows 79% to 88% of other metals in the wastewater are removed by POTWs. As explained above, EPA estimates 4.6 tons of other metals are also collectively discharged annually to POTWs. Thus POTWs collectively discharge approximately 1,280 lbs of other metals to surface waters annually. Following compliance with this proposed rule, the total amount of other metal discharges from POTWs nationwide to surface waters will be approximately 20 lbs or a reduction of 1,257 lbs. See TEDD for more details.

XVIII. Cost Effectiveness

EPA also conducted an analysis of the cost-effectiveness of the proposed option. For more information about the methodology, data, and results see the cost effectiveness section of the TEDD. The results of this cost-effectiveness analysis are expressed in terms of the costs (in 1981 dollars) per pound-equivalent removed, where pounds-equivalent removed for a particular pollutant is determined by multiplying the number of pounds of a pollutant removed by an option by a toxic weighting factor (TWF). The toxic weighting factors account for the differences in toxicity among pollutants and are derived using chronic aquatic life criteria (or toxic effect levels) and human health criteria (or toxic effect levels) established for the consumption of fish. For this proposal, EPA used the annual pounds removed for mercury, silver, tin, copper and zinc. The TWF for these pollutants is shown in Table XVIII–1.

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

Total Mercury	117.12
Silver	16.47
Tin	0.30
Copper	0.63
Zinc	0.05

EPA presents cost effectiveness in 1981 dollars as a reporting convention. This allows EPA to compare the cost-effectiveness of various ELGs. EPA calculates cost-effectiveness as the ratio of pre-tax annualized costs of an option to the annual pounds-equivalent removed by that option, and for this proposal is expressed as the average cost-effectiveness for the option. Average cost-effectiveness can be thought of as the ''increment'' between no regulation and the selected option for any given rule. The technology basis for PSES in this proposal has a cost-effectiveness ratio of $181–$201/lb-equivalent. This cost-effectiveness ratio falls within industry comparisons of PSES cost-effectiveness. A review of approximately 25 of the most recently promulgated or revised categorical pretreatment standards demonstrates that PSES cost effectiveness ranges from approximately $1/lb-equivalent (Inorganic Chemicals) to $380/lb-equivalent (Transportation Equipment Cleaning) in 1981 dollars.

TABLE XVIII–2—PSES COST EFFECTIVENESS ANALYSIS

Proposed option	Pre-tax total annualized costs ($1981 M)	Removals (lbs-eq)	Average cost effectiveness
ADA National Survey	$23	113,152	$201
Colorado Survey	21	113,152	181

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

XIX. 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. See DCN DA00148. 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 8,800 pounds (4.4 tons): 8,448 pounds are in the form of solid particles and 352 pounds (4%) are dissolved in the wastewater. Through POTW treatment, approximately 90% of dental mercury is removed from the wastewater and transferred to sewage sludge. The 10% of dental mercury not removed by POTW treatment is discharged to surface water. EPA estimates that POTWs annually discharge approximately 880 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%, or 6.7 billion pounds, are treated to produce biosolids for beneficial use as a soil amendment and applied to about 0.1% of agricultural lands in the United States (National Research Council, 2002). Approximately 4,800 pounds per year of dental mercury are contained in land applied biosolids.

Approximately 18%, or 2 billion pounds, of the sewage sludge generated annually by POTWs are surface disposed in facilities such as sewage sludge mono-fills or municipal landfills. Approximately 1,400 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%, or 2.5 billion pounds, of sewage sludge generated annually by POTWs is disposed of through incineration. An estimated 35 pounds of dental mercury are emitted to the atmosphere annually from incineration of sewage sludge (U.S. EPA, 2005); about 11.5 pounds of which are deposited within the conterminous United States (U.S. EPA, 1997). 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 sulfur reducing bacteria. Methylmercury is easily absorbed into muscle and fat tissues, but it is not readily excreted due to its low water solubility. Methylmercury thus has high potential to become increasingly concentrated up through aquatic food chains as larger fish eat smaller fish. 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 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. 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, mercury re-emitted from the oceans or soils, and mercury deposited 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 an environmental benefits analysis of this proposed 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 quantified economic benefits from improved human health and ecological conditions resulting from lower fish concentrations of methylmercury. See DCN DA00148. The proposed pretreatment standards will produce human health and ecological benefits by reducing the estimated annual nationwide POTW discharge of dental mercury to surface water from 880 pounds to 14 pounds.

XX. Non-Water Quality Environmental Impacts Associated With the Proposed Technology Basis

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 collection and treatment technologies on energy consumption, air pollution, and solid waste generation. EPA anticipates that the proposed rule would produce minimal non-water quality impacts. The Administrator has determined that these very minimal impacts are acceptable. For additional information on the analysis of these non-water quality impacts, see the Technical and Economic Development Document.

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 proposed rule standards. As described in Section VI, an amalgam separator in

a dental office is installed between chairs used for treatment and the vacuum pump. 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 a result, EPA expects operation of an amalgam separator would pose negligible additional energy requirements on the existing vacuum pump.

While the vendor data used to support this proposed rule have not identified incremental energy requirements for an amalgam separator, EPA is aware that some units described in the literature may require small pumps to remove settled effluent from the separator (DCN 00162). EPA found that these pumps are designed to operate only at the end of the day or overnight, when the vacuum system is turned off. Any incremental energy requirements in those cases where a small supplemental pump is installed would be negligible compared to the energy demands of the vacuum pump. Based on this evaluation of energy requirements associated with this proposed rule, EPA concludes there will be no significant non-water quality impacts associated with the energy requirements of this proposed rule.

B. Air Emissions

Unbound mercury is highly volatile and can easily evaporate into the atmosphere. An estimated 99.6% 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 proposed PSES and PSNS will not pose any increases in air pollution. EPA concludes there will be no significant non-water quality impacts associated with air emissions as a result of this proposed rule.

C. Solid Waste Generation

As explained above in Section XI, 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. This proposed rule is expected to increase the use of amalgam separators nationwide by one and a half times, since EPA estimates 40% of dental offices have separators installed, with a corresponding increase in collection of used amalgam prior to POTW discharge and recycling of amalgam via the spent separator canisters. EPA expects the operation and maintenance requirements associated with the amalgam separator compliance option included as part of the proposed rule will further promote recycling as the primary means of amalgam waste management. EPA expects this proposed rule will not create additional solid waste, but will instead result in a shift in how dental amalgam is handled. Nationally, EPA expects less dental amalgam will partition to the POTW wastewater sludge leading to reductions in the amount of mercury currently land applied, landfilled, or released to the air during incineration. Instead, it will be collected in separator canisters and recycled. Based on this evaluation of solid waste generation, EPA concludes there will be a reduction in non-water quality impacts associated with solid waste generation as a result of this proposed rule.

XXI. Implementation and Proposed Changes to General Pretreatment Regulations in 40 CFR Part 403

A. Implementation Deadline

1. Existing Sources

For existing sources, EPA proposes a compliance date of three years after the effective date of the final rule. Section 307(b)(1) of the CWA provides categorical pretreatment standards ''shall specify a time for compliance not to exceed three years from the date of promulgation.'' See also 40 CFR 403.6(b). In proposing a compliance date for existing sources subject to this proposed rule, EPA considered several factors. First, EPA considered the burden on Control Authorities (POTWs with approved Pretreatment Programs) of implementing this rule on an industry consisting of approximately 110,000 dental offices, many of whom are small businesses. EPA expects that these POTWs will need to develop and implement new strategies and programs for managing the enforcement and compliance of these pretreatment standards given that the number of possibly affected facilities is approximately 10 times the total number of dischargers currently regulated under any categorical pretreatment standard. EPA expects that POTWs will need time to conduct outreach to dental offices subject to this proposed rule. Moreover, EPA envisions that dental offices may use the entire three year period to come into compliance with the numeric standard (presumably using amalgam separators) and implement the required BMPs.

2. New Sources

For new sources, the compliance deadline is governed by EPA's regulation at 40 CFR 403.6(b), which provides that

> New Sources shall install and have in operating condition, and shall 'start-up' all pollution control equipment required to meet applicable Pretreatment Standards before beginning to Discharge. Within the shortest feasible time (not to exceed 90 days), new Sources must meet all applicable Pretreatment Standards.

B. Upset and Bypass Provisions

A ''bypass'' is an intentional diversion of the streams from any portion of a treatment facility. An ''upset'' is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. EPA's regulations for indirect dischargers concerning bypasses and upsets are set forth at 40 CFR 403.16 and 403.17.

C. Variances and Modifications

The CWA requires application of pretreatment standards established pursuant to sections 304 and 307 for all indirect dischargers. However, the statute provides for the modification of these national requirements in a limited number of circumstances. Moreover, the Agency has established administrative mechanisms to provide an opportunity for relief from the application of the national pretreatment standards for categories of existing sources.

1. Fundamentally Different Factors Variance

EPA may develop pretreatment standards different from the otherwise applicable requirements if an individual discharger 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. EPA, in its initial implementation of the effluent guidelines and standards program, provided for the FDF modifications in regulations. These were variances from the BCT effluent limitations, BAT limitations for toxic and nonconventional pollutants, and BPT limitations for conventional pollutants for direct dischargers. FDF variances for toxic pollutants were challenged judicially and ultimately sustained by

the Supreme Court. (*Chemical Manufacturers Association* v. *Natural Resources Defense Council,* 479 U.S.C. 116 (1985)).

Subsequently, in the Water Quality Act of 1987, Congress added new CWA section 301(n). This provision explicitly authorizes modifications of the otherwise applicable BAT effluent limitations or categorical pretreatment standards for existing sources if a discharger is fundamentally different with respect to the factors specified in CWA section 304 or 403 (other than costs) from those considered by EPA in establishing the effluent limitations or pretreatment standards. CWA section 301(n) also defined the conditions under which EPA may establish alternative requirements. Under section 301(n) of the CWA, an application for approval of a FDF variance must be based solely on (1) information submitted during rulemaking raising the factors that are fundamentally different or (2) information the applicant did not have an opportunity to submit. The alternate limitation or standard must be no less stringent than justified by the difference and must not result in markedly more adverse non-water quality environmental impacts than the national limitation or standard.

EPA regulations at 40 CFR part 403, authorizing the Regional Administrators to establish alternative standards, further detail the substantive criteria used to evaluate FDF variance requests for existing dischargers to POTWs. Thus, 40 CFR 403.13(d) identifies six factors (e.g., volume of process wastewater, age and size of a discharger's facility) that may be considered in determining if a discharger is fundamentally different. The Agency must determine whether, based on one or more of these factors, the discharger in question is fundamentally different from the dischargers and factors considered by EPA in developing the nationally applicable pretreatment standards. The regulation also lists four other factors (e.g., inability to install equipment within the time allowed or a discharger's ability to pay) that may not provide a basis for an FDF variance. In addition, under 40 CFR 403.13(c)(2), a request for standards less stringent than the national standard may be approved only if compliance with the pretreatment standards would result in either (a) a removal cost wholly out of proportion to the removal cost considered during development of the pretreatment standards, or (b) a non-water quality environmental impact (including energy requirements) fundamentally more adverse than the impact considered during development of the pretreatment standards. The legislative history of section 301(n) of the CWA underscores the necessity for the FDF variance applicant to establish eligibility for the variance. EPA's regulations at 40 CFR 403.13 are explicit in imposing this burden upon the applicant. The applicant must show that the factors relating to the discharge controlled by the applicant's permit which are claimed to be fundamentally different are, in fact, fundamentally different from those factors considered by EPA in establishing the applicable pretreatment standards. In practice, very few FDF variances have been granted for past ELGs. An FDF variance is not available to a new source subject to PSNS.

2. Economic Variances

Section 301(c) of the CWA authorizes a variance from the otherwise applicable PSES and PSNS for nonconventional pollutants due to economic factors. As this rule controls toxic pollutants and only controls nonconventional pollutants that are also found in the same waste stream, this variance would not be applicable to this particular rule.

D. What are the roles of key entities involved in implementing the rule and how are pretreatment standards implemented?

EPA recognizes the role of many interested parties in the development of, and, ultimately, the successful implementation of pretreatment standards for dental dischargers. To the greatest extent possible, EPA has attempted to strike a reasonable balance among the many interests. A short summary of the various roles involved in implementing categorical pretreatment standards is provided below.

1. Control Authorities

The ''Control Authority'' refers to the POTW if the POTW has an approved Pretreatment Program, or the Approval Authority if it has not been approved, which may be the state or EPA. A POTW is a treatment works as defined by section 212(2) of the CWA, which is owned by a state or municipality (as defined in CWA sections 502 (3) and (4), respectively). (see 40 CFR 403.3(q).) POTWs collect wastewater from homes, commercial buildings, and industrial facilities and typically transport it via a series of pipes, known as a collection system, to the treatment plant. Most POTWs are not designed to treat the toxics in commercial and industrial wastes, which can cause pass through, interfere with, or are otherwise incompatible with the operation of POTWs, including sludge disposal methods at POTWs. The General Pretreatment Regulations require POTWs that meet certain criteria (e.g. minimum design flow) to develop Pretreatment Programs to control industrial Discharges into their sewage collection systems, unless the state exercises its option to assume local responsibilities as provided in EPA's regulations at 40 CFR 403.10(e) and (f). Today there are an estimated 1500 approved POTW Pretreatment Programs. As required under 40 CFR part 403, Control Authorities implement and enforce control mechanisms (*e.g.,* permits) to the Industrial Users (IUs) that discharge to their systems, inspect and sample, and enforce control requirements in order to protect the POTW against discharges which ''pass through'' or cause interference'' with the POTW (see 40 CFR 403.3(p) and (k)).

2. Approval Authority

The Director in an NPDES state with an approved state Pretreatment Program may be authorized to serve as the Approval Authority for the implementation of a general pretreatment program. (40 CFR 403.3(c)). Thirty-six states have such approved Pretreatment Programs and are authorized to serve as Approval Authorities for implementation of the Pretreatment Program. In a non-NPDES state or an NPDES state without an approved state Pretreatment Program, the EPA Regional Administrator is the Approval Authority.

3. EPA

EPA establishes and implements national regulations for Pretreatment Programs and categorical pretreatment standards for certain industries such as the pretreatment standards for dental amalgam proposed today. EPA also develops policy and guidance and provides training and oversight for Pretreatment Program implementation. As noted above, EPA's Regional Administrator serves as the Approval Authority for a non-NPDES state or an NPDES state without an approved state Pretreatment Program, and as the Control Authority for POTWs without an approved Pretreatment Program in these states.

4. Industrial Dischargers (i.e. Dentists)

IUs of POTWs must comply with Pretreatment Standards prior to introducing pollutants into a POTW. The General Pretreatment Regulations include general prohibitions that forbid IUs from causing pass through and interference (i.e., cause the POTW to

violate its permits limits, or interfere with the operation of the POTW or the beneficial use of its sewage sludge), and specific prohibitions against the discharge of pollutants that cause problems at the POTW such as corrosion, fire or explosion, and danger to worker health and safety. As discussed in this document, EPA may also develop national categorical pretreatment standards, including numeric pollutant limits and BMPs, for IUs in specific industrial categories. The General Pretreatment Regulations include reporting and other requirements necessary to implement these categorical standards (*e.g.,* 40 CFR 403.12).

E. What are the Control Authority requirements under existing General Pretreatment Regulations?

The current regulations require certain minimum oversight of IUs by Control Authorities, which are typically POTWs with Approved Pretreatment Programs but could be states or EPA acting as Pretreatment Control Authorities. The required minimum oversight includes receipt and analysis of reports and other notices submitted by IUs, randomly sampling and analyzing effluent from IUs, and conducting surveillance activities to identify occasional and continuing non-compliance with pretreatment standards. In addition, for IUs designated as significant industrial users (SIUs), per 40 CFR 403.3(v), 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 with a duration not to exceed five years (40 CFR 403.8(f)(1)(iii) and 403.8(f)(2)(v), 403.10(e) and 403.10(f)(2)(i)). Control authorities may determine that an industrial user is a non-significant categorical industrial user or that an industrial user is not an SIU (see 40 CFR 403.3(v)(2) and (v)(3)).

Facilities that are subject to categorical pretreatment standards contained in regulations in 40 CFR Chapter I, subchapter N are referred to as Categorical Industrial Users (CIUs). The regulations related to SIU at 40 CFR 403.3(v) define SIU to include CIUs, but also provide that a Control Authority may determine that a CIU may be a Non-Significant Categorical Industrial User (NSCIU) if certain conditions are met. (see 403.3(v)(1) and (v)(2)). State Approval Authorities and POTW Control Authorities who have the legal authority to implement the NSCIU classification may find some of their CIUs satisfy the qualifying conditions of NSCIU at 40 CFR 403.3(v)(2). Upon such finding, the Control Authority may exclude facilities meeting the NSCIU criteria from the SIU definition and its minimum oversight requirements. A Control Authority may not exclude CIUs from the requirements of the categorical pretreatment standards.

F. Why is EPA revising the existing General Pretreatment Regulations?

EPA proposes to amend selected parts of the General Pretreatment Regulations in order to simplify oversight requirements for the approximately 110,000 dental offices subject to this proposed rule. As mentioned in paragraph E. of this section, when EPA promulgates categorical industrial pretreatment standards, as defined in 40 CFR part 403, affected dischargers are referred to as Categorical Industrial Users (CIUs). The number of dental offices that would be subject to this proposed rule is approximately ten times the current number of Categorical Industrial Users. EPA recognizes regulatory oversight of this increased number of CIUs would need to be very different from regulating the current number of CIUs. Using the existing regulatory framework, enforcement of categorical pretreatment regulation on this industry would require an increase in local, state and federal resources whereas EPA does not expect such efforts to result in greater environmental benefit. EPA is focused on providing technical means to reduce administrative burden to dentists and Control Authorities, while still providing a clear understanding of who is affected and what they are expected to do, as well as achieving the projected pollutant reductions. EPA estimates that these changes to the Existing General Pretreatment Standards would reduce costs to POTWs to implement and enforce this proposed rule by $47 million annually (see TEDD).

G. What changes is EPA proposing to the General Pretreatment Standards?

EPA proposes a new classification of CIU specifically tailored to the Dental Office Effluent Limitations Guidelines and Standards rule, ''Dental Industrial User'' (DIU). EPA proposes that such Users not be subject to the oversight requirements for SIUs (*i.e.,* control mechanism issuance requirement, annual inspection and sampling requirements). Rather, EPA proposes to allow Control Authorities to focus their oversight efforts on those dental office facilities that fail to meet the compliance requirements of the DIU.

H. When is a dental office a DIU?

Under the proposed rule, a dental discharger is given the option of complying with monitoring and reporting requirements in 40 CFR 441.60, which are tailored for dental dischargers, in lieu of the otherwise applicable monitoring and reporting requirements in 40 CFR part 403. If a dental discharger complies with (1) the special monitoring and reporting requirements in 40 CFR 441.60, (2) the remaining 40 CFR part 403 requirements, and the applicable pretreatment standards (PSES or PSNS), then the Control Authority may treat the dental discharger as a DIU. The DIU must maintain compliance in order to retain its DIU status.

I. When is a dental office not a DIU?

If the dental office does not meet the requirements to be treated as a DIU, under this proposal the Control Authority must treat the dental discharger as a Significant Industrial User as defined in 40 CFR 403.3(v). As a Significant Industrial User, the POTW Control Authority would be required to conduct the oversight duties applicable to SIUs as described in 40 CFR 403.8(f).

J. What oversight responsibilities for DIUs is EPA proposing for Control Authorities?

This proposal would require that a Control Authority evaluate, at least once per year, whether an IU previously determined to be a DIU still meets the criteria for treatment as a DIU under 40 CFR 441.60. EPA anticipates that this evaluation will primarily involve the Control Authority's verification that the certification has been submitted by the dental office documenting continued eligibility for DIU status. In accordance with 40 CFR 403.8(f)(2)(viii)(F), a dental discharger would be in significant noncompliance if it fails to provide any required report within 45 days of the due date or if the Control Authority elects to inspect the facility and finds the facility is not in compliance with 40 CFR 441.60. Upon discovery that a dental office is not in compliance with regulations at 40 CFR 441.60 (either reporting requirements, 403, or 441 PSES/PSNS requirements), the Control Authority must initiate enforcement in accordance with its approved Pretreatment Program to return the dental discharger into compliance. In order for the Control Authority to continue to treat the dentist as a DIU, the Control Authority would need to verify and find, through an inspection, that the dental discharger has returned to full compliance with the criteria in 40

CFR 441.60. If, within 90 days, the Control Authority inspects, verifies, and finds that the dental discharger has returned to full compliance with 40 CFR 441.60, then the dental discharger would remain a DIU. The 90 day compliance deadline is consistent with other portions of 40 CFR part 403 (e.g., significant noncompliance compliance report deadlines, 90 day report after effective dates of categorical standards), and provides both the dental discharger and Control Authority with an incentive to provide a timely return to compliance. If the dental discharger has not returned to compliance within 90 days of the initial noncompliance, the Control Authority could no longer treat the dental discharger as a DIU and the dental discharger would become a Significant Industrial User. Control Authorities are required to provide oversight of SIUs which includes inspection and sampling of each SIU annually, reviewing the need for a slug control plan, and issuing a Permit or equivalent control mechanism with a duration not to exceed five years (40 CFR 403.8(f)(1)(iii) and (f)(2)(v) and 403.10(f)(2)(i)).

K. Can a dental office DIU be a Non-Significant Industrial User (NSCIU)?

EPA does not propose to prohibit a Control Authority from finding that a dental office may qualify as an NSCIU on an individual basis. State Approval Authorities and POTW Control Authorities who have the legal authority to implement the NSCIU classification may find that one or more of their dental office CIUs may qualify as NSCIUs. However, since its promulgation in 2005, many state Approval Authorities and POTW Control Authorities have not adopted regulations to implement the NSCIU classification. EPA believes that the DIU classification, tailored for this single categorical pretreatment standard, while comparable to the NSCIU classification, would be preferable, because it would significantly reduce the Control Authority's burden in complying with the oversight requirements that would otherwise apply.

L. Can Dental Industrial Users be covered under a general permit?

Although this proposed rule does not require a Control Authority to regulate DIUs as SIUs thereby requiring the Control Authority to issue a control mechanism, designation of a dental office subject to 40 CFR part 441 as a DIU does not preclude a Control Authority's option to regulate the dental office under a general control mechanism, 40 CFR 403.8(f)(1)(iii)(A), if that legal authority is adopted. The General Pretreatment Regulations describe conditions which must be met in order for the Control Authority to use a general control mechanism in lieu of an individual permit or control mechanism. Provided that the Control Authority adopted the necessary legal authority and modified its Pretreatment Program to incorporate such authority and procedures, the Control Authority may use a general control mechanism or ''general permit'' for facilities that meet certain minimum criteria for being considered substantially similar. The use of general control mechanisms allows the permitting authority to allocate resources in a more efficient manner and to provide timelier permit coverage, particularly in the circumstances of covering large numbers of similar facilities under a single mechanism. EPA considers that most dental offices generally will conform to these requirements and could appropriately be covered by a general control mechanism issued by a Control Authority. The use of a general control mechanism also ensures consistency of permit conditions for similar facilities. Additional information on the use of general control mechanisms may be found in the **Federal Register** of October 14, 2005 (70 FR 60143).

M. Would any POTW with a dentist office in its service area be required to develop a Pretreatment Program?

In accordance with 40 CFR 403.8(a), POTWs (or combination of POTWs operated by the same authority) with a total design flow greater than 5 million gallons per day and receiving pollutants from IUs which pass through or interfere with the operation of the POTW or are otherwise subject to Pretreatment Standards are required to establish a POTW Pretreatment Program unless the state with an approved Pretreatment Program exercises its option to assume local responsibilities as provided for in 40 CFR 403.10(e). For smaller POTWs, POTWs that have a design flow of 5 million gallons per day or less, the Regional Administrator or state Director may require the POTW to develop a local Pretreatment Program if the nature or volume of the industrial influent, treatment process upsets, violations of POTW effluent limitations, contamination of municipal sludge, or other circumstances warrant such development in order to prevent interference or pass through. Interference and pass through are defined at 40 CFR 403.3(k) and (p), respectively. As noted above, a state with an Approved state Pretreatment Program may instead assume local responsibilities as provided in 40 CFR 403.10(e). EPA anticipates that the approved states will choose to carry out the oversight activities themselves rather than requiring a POTW to develop a full Pretreatment Program solely to regulate its dental dischargers.

N. Would states or municipalities that already implement Dental Amalgam Control Programs need to modify their regulations?

The proposed rulemaking would not affect existing state and local requirements that control discharges of dental amalgam. However, states with approved state programs and POTWs with approved Pretreatment Programs would need to enforce the federal requirements at a minimum. The new federal requirements include removal of at least 99.0% of total mercury from amalgam discharges which can be accomplished through proper use of a 2008 ISO 11143 certified amalgam separator with a removal efficiency of at least 99.0%. The proposal at part 441.40(d) would allow dentists currently operating amalgam separators no less efficient than 95% to continue to operate their separators for ten years before they would be required to meet the 99% removal standard. Where ongoing state or POTW Control Authority programs require additional information or implementation requirements, the Control Authority must implement and enforce both program requirements and, for overlapping requirements, the more stringent of the two programmatic requirements.

O. Will states or municipalities that already implement Dental Amalgam Control Programs need to issue control mechanisms or permits to impose requirements that are more stringent than the federal requirements?

The legal authority requirements for a POTW Pretreatment program only require issuance of an individual or general control mechanism to SIUs, 40 CFR 403.8(f)(2)(1)(iii)(A). The proposed regulation modification in the General Pretreatment Regulations is to establish a new DIU classification of Industrial User. The proposal indicates that a DIU will not be a Significant Industrial User. Where the state or POTW existing dental amalgam control programs are equal to or less stringent than this proposal, and the state or Control Authority adopt and have their Pretreatment Programs appropriately approved to incorporate EPA's DIU provisions, dental offices compliant

with the DIU classification will not need to be issued a control mechanism.

P. What reports would dental dischargers be required to submit?

Existing and new dental dischargers could comply with the special reporting requirements in 40 CFR part 441 in lieu of the otherwise applicable reporting requirements in 40 CFR part 403 by submitting the Baseline Report (40 CFR 441.60(a)(1)) and the 90 Day Compliance Report (40 CFR 441.60(a)(2)) and Periodic Monitoring reports (40 CFR 441.60(a)(3)). Submission of these reports would satisfy the reporting requirements in 40 CFR parts 403 and 441. Dental dischargers who do not submit reports consistent with the requirements in 40 CFR 441.60 would be required to submit the reports described in 40 CFR 403.12(b), (d), and (e).

Q. Can the DIU designate a contractor or contract vendor to submit Compliance Reports to the Control Authority or EPA?

In accordance with 40 CFR 403.12(l), Baseline Monitoring Reports, 90-day Compliance Reports, and Periodic monitoring reports (40 CFR 403.12(b), (d), and (e), respectively) must be signed by (1) a responsible corporate officer of the IU if it is a corporation; (2) a general partner or proprietor if the IU is a partnership or sole proprietorship; or (3) a duly authorized representative of the responsible corporate officer, general partner, or proprietor if the authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the industrial discharge originates, such as the position of plant manager or a position of equivalent responsibility for environmental matters for the company and the written authorization is submitted to the Control Authority.[28] This does not preclude a third-party from submitting the reports as long as the submission includes the proper signature from the DIU.

R. Would Control Authorities need to modify their Sewer Use Ordinance and state regulations, respectively, to incorporate these changes to 40 CFR part 403?

The proposed changes to 40 CFR part 403 to create the DIU classification are changes that the Control Authority may adopt at its discretion. The changes to 40 CFR part 403 provide program flexibility and are not required to be incorporated into the state or POTW's Pretreatment Program. However, for Control Authorities to designate dental offices as DIUs, the state and POTW Pretreatment program would need to incorporate these changes into their legal authority under 40 CFR 403.8(f)(l).

XXII. Statutory and Executive Order Reviews

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' Accordingly, EPA submitted this action to the OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The information collection requirements in this proposed 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 2514.01. To reduce the overall costs associated with this rule, in lieu of discharge monitoring, proposed 40 CFR 441.60 allows dentists to certify compliance with requirements for amalgam capture and certain BMPs.

For purposes of this estimate, EPA assumed all affected dentists would elect to comply with this proposal through certification rather than discharge monitoring. EPA estimates it would take a total annual average of 153,000 hours[29] and $2.5 million for affected dental offices to collect and report the information required for certification in the proposed rule. This estimate includes effort for each dental office associated with completing the baseline monitoring report, a one-time compliance report and an annual compliance certification for each year of a three year ICR. This estimate is based 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 17,400 hours and $960,000 for control authorities to review the information submitted by dentists that certify they meet the requirements in the proposed rule. 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 in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this proposed rule, which includes this ICR, under Docket identification ID number EPA–HQ–OW–2014–0693. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** section in this document for where to submit comments to EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after October 22, 2014, a comment to OMB is best assured of having its full effect if OMB receives it by November 21, 2014. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) A small business in the Dental Office sector (NAICS 621210) with annual receipts of 7 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.

EPA estimates that 109,600 dental offices out of 109,859 dental offices potentially subject to this proposal meet the small business definition. EPA's analysis of projected impacts on small dental offices is described in detail in

[28] Today's proposal does not apply to third-party vendors because they are not dental dischargers, and therefore, as such, EPA cannot compel a third-party vendor to meet any reporting requirements.

[29] This estimate reflects approximately three hours per office in the first year and one hour each subsequent year.

Section XVI. EPA projects less than 1% of 109,859 affected dental offices would incur compliance costs exceeding 1% of revenue and no more than 0.2% would incur compliance costs exceeding 3% of revenue. After considering the economic impact of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Although this proposed 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 proposed rule on small entities. First, while some amalgam separators currently used at some dentists are certified to meet slightly less mercury removal than required in this proposed rule (e.g., they are certified to remove 95% total mercury), this proposal would allow dentists with existing separators to satisfy the requirements for a period of up to 10 years. See Section XIV. In addition, this proposed rule includes a compliance option that would allow dental offices subject to the rule to certify proper operation of a widely available, inexpensive technology that meets certain requirements in combination with BMPs in lieu of conducting more onerous discharge monitoring requirements that would otherwise be associated with pretreatment standards. Finally, EPA has tried to minimize impacts to small governments responsible for Pretreatment Programs by proposing to amend the General Pretreatment Regulations to create the DIU classification. The DIU classification reduces oversight responsibilities for Control Authorities from the current regulatory scheme, while at the same time achieving the projected pollutant reductions. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any 1 year. As explained in Section XVI, the annual cost of the proposed rule is $44–$49 million. Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

The proposal 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 proposal would impact government entities required to administer the proposed pretreatment standards, EPA does not expect that this would include any small governments. 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). As explained in Section XXI, control authorities are responsible for oversight and administration associated with this proposal. To qualify as a Control Authority, a POTW must have a flow of at least 5 million gallons per day. 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 would meet the definition of a Control Authority.

E. Executive Order 13132: Federalism

This proposed rule would not have federalism implications. It would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The proposed rule would not alter the basic state-federal scheme established in the CWA under which EPA authorizes states to carry out the NPDES permit program. EPA expects the proposed rule would have little effect on the relationship between, or the distribution of power and responsibilities among, the federal and state governments. Thus, Executive Order 13132 does not apply to this proposed rule.

EPA coordinated closely with states, via ECOS and local governments and with NACWA, throughout the development of this proposed rule. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed rule from state and local officials.

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

This proposed rule does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 6, 2000). It would 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 proposed 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 rule. EPA specifically solicits additional comment on this proposed action from Tribal officials.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to rules that are economically significant according to Executive Order 12866 and involve a health or safety risk that may disproportionately affect children. This action is not subject to Executive Order 13045 because it is estimated to cost less than $100 million and does not involve a safety or health risk that may have disproportionately negative effects on children. The proposed 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 proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy, as described in Section XX of this proposal. 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 Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, (Pub. L. 104–113; 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking involves technical standards. The International Organization for Standardization (ISO) developed efficiency standards for amalgam separators (ISO 11143) in 1999 and updated these standards in 2008. EPA proposes to use ISO 11143 2008. This voluntary standard setting organization established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam mercury using specified test procedures in a laboratory setting. It also includes requirements for instructions for use and operation and maintenance.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

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

Executive Order 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. 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, the proposal would 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. The proposed 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.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potential environmental justice considerations associated with this proposed regulation.

List of Subjects in 40 CFR Parts 403 and 441

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

Dated: September 23, 2014.

Gina McCarthy,

Administrator.

Therefore, it is proposed that 40 CFR parts 403 and 441 be amended as follows:

PART 403—GENERAL PRETREATMENT REGULATIONS FOR EXISTING AND NEW SOURCES OF POLLUTION

■ 1. The authority citation for part 403 continues to read as follows:

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

■ 2. In § 403.3, add paragraph (v)(4) to read as follows:

§ 403.3 Definitions.

* * * * *

(v) * * *

(4) An industrial user subject to categorical Pretreatment Standards under 40 CFR part 441 is designated a Dental Industrial User (DIU) rather than a Significant Industrial User (SIU) if the Industrial User (IU) has complied with 40 CFR part 403, the applicable pretreatment standards for existing sources (PSES) or pretreatment standards for new sources (PSNS) and the monitoring and reporting requirements of 40 CFR 441.60. If a DIU has not complied with these requirements and standards, such IU will be considered a SIU until the Control Authority evaluates the IU as specified in § 403.8(f)(2)(v)(D).

* * * * *

■ 3. In § 403.8, add paragraph (f)(2)(v)(D) to read as follows:

§ 403.8 Pretreatment Program Requirements: Development and Implementation by POTW.

* * * * *

(f) * * *

(2) * * *

(v) * * *

(D) Where the publicly owned treatment works (POTW) finds that an Industrial User (IU) meets the criteria for classification as a Dental Industrial User (DIU), the POTW must evaluate, at least once per year, whether the IU meets the criteria in § 403.3(v)(4). In the event that the POTW determines that a DIU does not meet the criteria in § 403.3(v)(4), the POTW must immediately begin enforcement in accordance with its enforcement response plan. If the dental discharger has not returned to compliance within 90 days of the initial noncompliance, the POTW may no longer treat the dental discharger as a DIU and must treat the dental discharger as a SIU. Upon verification by the POTW through an inspection and a finding that the dental discharger has complied with all of the applicable requirements in § 403.3(v)(4), the dental discharger may be considered a DIU.

* * * * *

■ 4. Add part 441 to read as follows:

PART 441—DENTAL OFFICE (MERCURY AMALGAM) POINT SOURCE CATEGORY

Sec.
441.10 Applicability.
441.20 General definitions.
441.30 General pretreatment requirements.
441.40 Pretreatment standards for existing sources (PSES).
441.50 Pretreatment standards for new sources (PSNS).
441.60 Discharge monitoring, reporting, and recordkeeping requirements.

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

§ 441.10 Applicability.

(a) Except as provided in paragraphs (b) and (c) of this section, the provisions of this part are applicable to discharges of wastewater to publicly owned treatment works from facilities where the practice of dentistry is performed (''dental dischargers''), including but not limited to institutions, permanent or temporary offices, clinics, mobile units, home offices, and facilities, and including dental facilities owned and operated by Federal, state, or local governments.

(b) The provisions of this part do not apply to process wastewater discharges from dental dischargers which exclusively practice one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics;

(c) Dental Dischargers will be exempt from any further requirements of this rule so long as they:

(1) Do not place or remove amalgam except in limited emergency circumstances

(2) Certify to the Control Authority that that they do not and will not use or remove amalgam, including the following information:

(i) The facility name, address, contact information.

(ii) The dental license number of all practicing dentists at the location.

(3) Notify the Control Authority of any changes to information required under paragraphs (c)(2)(i) and (ii) of this section.

(4) Information provided to comply with paragraphs (c)(2)(i) and (ii) of this section must be signed by the responsible corporate officer as defined in § 403.12(l).

§ 441.20 General definitions.

For purposes of this part:

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

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

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

Dental amalgam means an alloy of elemental mercury and other metals that is used in the practice of dentistry.

Dental Discharger means a source of wastewater to a publicly owned treatment works from a facility where the practice of dentistry is performed as described in 40 CFR 441.10.

Dental Industrial User (DIU) means a dental discharger as described in § 441.10(a) that meets the requirements of 40 CFR 441.60.

§ 441.30 General pretreatment requirements.

(a) Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

(b) [Reserved]

§ 441.40 Pretreatment standards for existing sources (PSES).

Except as provided in 40 CFR 403.7 (removal credits) and 403.13 (fundamentally different factors) and no later than [DATE 3 YEARS AFTER EFFECTIVE DATE OF THE FINAL RULE IN THE FEDERAL REGISTER], any existing source subject to this part must achieve the following pretreatment standards:

(a) Removal of at least 99.0% of total mercury from amalgam process wastewater and

(b) Incorporation of the following best management practices:

(1) Scrap amalgam (contact and non-contact), including but not limited to dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, or collection devices may not be flushed down the drain.

(2) Chair-side traps that may drain to a sewer must be cleaned with non-bleach, non-chlorine containing cleaners that have a pH of 6 to 8. Such cleaning must be conducted at least weekly.

(3) Certification that the BMPs specified in paragraphs (b)(1) and (2) of this section are being followed is deemed to meet these requirements.

(c) The requirements of paragraph (a) of this section may be met by installation and operation of at least one 2008 ISO 11143 certified amalgam separator that:

(1) Is certified to meet a removal efficiency of no less than 99.0%;

(2) Receives all amalgam process wastewater;

(3) Is sized to incorporate all wastewater that may pass through it;

(4) Is inspected at least once per month to ensure proper operation and maintenance of the separator, including confirmation that amalgam process wastewater is flowing through the retaining cartridge, separator canister, or amalgam separating portion of the amalgam separator (preventing bypass);

(5) In the event that the separator is found to not be functioning properly, is repaired or replaced according to manufacturer instructions; and

(6) Is regularly maintained by replacing the amalgam retaining cartridge(s), separator canister(s), or separator unit(s) whenever the collection of retained solids reaches the manufacturer's stated design capacity or annually, whichever comes first.

(d) Dental Dischargers that operate an amalgam separator certified under the 1999 or 2008 ISO 11143 standard installed at a dental facility prior to October 22, 2014, satisfy the requirements of paragraph (a) of this section until [DATE 10 YEARS AFTER EFFECTIVE DATE OF THE FINAL RULE IN THE FEDERAL REGISTER] if the existing amalgam separator:

(1) Receives all amalgam process wastewater;

(2) Is sized to incorporate all amalgam process wastewater that may pass through it;

(3) Is inspected at least once per month to ensure proper operation and maintenance of the separator, including confirmation that wastewater is flowing through the retaining cartridge, separator canister, or amalgam separating portion of the amalgam separator (preventing bypass); and

(4) Is regularly maintained by replacing the amalgam retaining cartridge(s), separator canister(s), or separator unit(s) whenever the collection of retained solids reaches the manufacturer's rated design capacity or annually, whichever comes first.

§ 441.50 Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7 (removal credits) and 40 CFR 403.13 (fundamentally different factors), any new source subject to this part must achieve PSNS as follows:

(a) Removal of at least 99.0% of total mercury from amalgam process wastewater and

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

(1) Scrap amalgam (contact and non-contact), including but not limited to dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, or collection devices may not be flushed down the drain.

(2) Chair-side traps that may drain to a sewer must be cleaned with non-bleach, non-chlorine containing cleaners that have a pH of 6 to 8. Such cleaning must be conducted at least weekly.

(3) Certification that the BMPs specified in (1) and (2) of this subpart are being followed is deemed to meet these requirements.

(c) The requirements of paragraph (a) of this section may be met by installation and operation of at least one 2008 ISO 11143 certified amalgam separator that:

(1) Is certified to meet a removal efficiency of no less than 99.0%;

(2) Captures all amalgam process wastewater;

(3) Is sized to incorporate all amalgam process wastewater that may pass through it;

(4) Is inspected at least once per month to ensure proper operation and maintenance of the separator, including confirmation that amalgam process wastewater is flowing through the retaining cartridge, separator canister, or amalgam separating portion of the amalgam separator (preventing bypass);

(5) In the event that the separator is found to not be functioning properly, is repaired or replaced according to manufacturer instructions; and

(6) Is regularly maintained by replacing the amalgam retaining cartridge(s), separator canister(s), or separator unit(s) whenever the collection of retained solids reaches the manufacturer's stated design capacity or annually, whichever comes first.

§ 441.60 Discharge monitoring, reporting, and recordkeeping requirements.

(a) Dental dischargers may comply with the following monitoring and reporting requirements in lieu of the otherwise applicable requirements in § 403.12(b), (d), and (e).

(1) *Baseline report.* For existing sources, a baseline report must be

submitted within 180 days of the effective date of this rule. For new sources, a baseline report must be submitted at least 90 days prior to commencement of discharge. It must include:

(i) The facility name, address, and contact information as well as the dental license number of all practicing dentists at the location.

(ii) A description of the operation at the dental discharger including:

(A) The total number of chairs,

(B) The total number of chairs at which dental amalgam may be present in the resulting wastewater;

(C) For existing sources, a description of any existing amalgam separators currently operated to include, at a minimum, the make, model, and manufacturers recommended frequency of container change. If no separators are currently employed, indicate none. For new sources, a description of any planned amalgam separators to include, at a minimum, the make, model, and manufacturers recommended frequency of container change.

(iii) For existing sources, statement of whether or not the facility currently employs the best management practices (BMPs) specified in § 441.40(b).

(2) *90-day compliance report.* For existing sources, a compliance report must be submitted within [90 days after the final compliance date of this rule]. For new sources, a compliance report must be submitted within 90 days following commencement of the introduction of wastewater into the publicly owned treatment works (POTW). The report must include:

(i) The facility name, address, and contact information as well as the dental license number of all practicing dentists at the location.

(ii) A description of the operation at the dental office including:

(A) The total number of chairs, and

(B) The total number of chairs at which dental amalgam may be present in the resulting wastewater.

(C) A description of any existing amalgam separators currently operated to include, at a minimum, the make, model, and manufacturers recommended frequency of container change.

(iii) Certification that the design and operation of separators meet the requirements specified in § 441.40 or § 441.50, as applicable.

(iv) Certification that the facility is employing BMPs specified in § 441.40(b) or § 441.50(b), as applicable.

(3) *Periodic monitoring report.* A periodic report of ongoing compliance must be submitted annually. The reports must include:

(i) The facility name, address, and contact information as well as the dental license number of all practicing dentists at the location;

(ii) If no changes have occurred since submission of the most recent compliance submission (e.g. 90-day compliance report or periodic monitoring report);

(iii) Certification that the design and operation of the separators meets the requirements specified in § 441.40 or § 441.50, as applicable and that the facility is employing the BMPs specified in § 441.40(b) or § 441.50(b), as applicable;

(iv) If changes have occurred since submission of the most recent compliance submission (e.g. 90-day compliance report or periodic monitoring report), you must submit the updated information required for the 90-day compliance report as specified in § 441.60(a)(2).

(b) If the dental discharger complies with the applicable requirements in 40 CFR part 403 and the monitoring and reporting requirements described in paragraphs (a)(1) through (3) of this section, in addition to the applicable pretreatment standards for existing sources (PSES) or pretreatment standards for new sources (PSNS) in § 441.40 or § 441.50, the dental discharger may be considered a Dental Industrial User (DIU) by the Control Authority; otherwise the Control Authority must treat the dental discharger as a Significant Industrial User (SIU) as defined in 40 CFR 403.3(v). Reports submitted to comply with this section must be signed by the responsible corporate officer as defined in 40 CFR 403.12(l).

(c) Dental dischargers must maintain on site and available for inspection (in either physical or electronic form) the following records for a period of three years from the date they are created:

(1) The baseline report required in paragraph (a)(1) of this section;

(2) The 90-day compliance report required in paragraph (a)(2) of this section;

(3) The periodic monitoring report required paragraph (a)(3) of this section;

(4) Documentation including the date of each visual inspection of the amalgam separator(s) as specified in § 441.40(c)(4) or § 441.50(c)(4), including records of visual inspections of the amalgam separator to ensure that the device is not in bypass mode;

(5) Documentation specifying the date of amalgam retaining cartridge replacement in accordance with § 441.40(c)(5) or § 441.50(c)(5); and

(6) Records indicating the date of amalgam retaining cartridges are sent off site for proper disposal and the shipping address of the facility to which amalgam retaining cartridges are sent.

[FR Doc. 2014–24347 Filed 10–21–14; 8:45 am]

BILLING CODE 6560–50–P