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Technical and Economic Development Document for the Final Effluent Limitations Guidelines and Standards for the Dental Category

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Chapter 1
Background

This chapter provides background information on the development of final effluent limitations guidelines and standards (ELGs) for the dental category. Chapters 1.1 and 1.2 present the legal authority and discuss the regulatory background for the final rule, respectively. Chapter 1.3 provides a history of activities related to the dental category rulemaking.

1.1 Legal Authority

The U.S. Environmental Protection Agency (EPA) is promulgating ELGs for the dental category (40 CFR 441) under the authorities of sections 101, 301, 304, 306, 307, 308, and 501 of the Clean Water Act (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.

1.2 Regulatory Background

1.2.1 Clean Water Act

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

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

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

The CWA also authorizes EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges from facilities that discharge wastewater indirectly, by sending wastewater to publicly owned treatment works (POTWs), as outlined in sections 304(g) and 307(b), (c) of the CWA. EPA establishes national pretreatment standards for those pollutants that may pass through, interfere with, or may otherwise be incompatible with POTW operations. CWA sections 307(b) and (c) and 304(g). The legislative history of the 1977 CWA amendments explains that pretreatment standards are technology-based and analogous to technology-based effluent limitations for direct dischargers for the removal of toxic pollutants. As further explained in the legislative history, the combination of pretreatment and treatment by the POTW is intended to achieve the level of treatment that would be required if the industrial source were making a direct discharge.[1] As such, in establishing pretreatment standards, EPA's consideration of pass through for national technology-based categorical pretreatment standards differs from that described in EPA's General Pretreatment Regulations at 40 CFR 403. For categorical pretreatment standards, EPA's approach for pass through satisfies two competing objectives set by Congress: (1) That standards for indirect dischargers be equivalent to standards for direct dischargers; and (2) that the treatment capability and performance of the POTWs be recognized and taken into account in regulating the discharge of pollutants from indirect dischargers. CWA 301(b)(1)(A)(BPT); and 301(b)(1(E).

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

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

[1] Conf. Rep. No. 95-830, at 87 (1977), reprinted in U.S. Congress. Senate. Committee on Public Works (1978), A Legislative History of the CWA of 1977, Serial No. 95-14 at 271 (1978).

1. Best Available Technology Economically Achievable (BAT)

   BAT represents the second level of stringency for controlling direct discharge of toxic and nonconventional pollutants. In general, BAT-based effluent guidelines and new source performance standards represent the best available economically achievable performance of facilities in the industrial subcategory or category. Following the statutory language, EPA considers the technological availability and the economic achievability in determining what level of control represents BAT. CWA section 301(b)(2)(A). Other statutory factors that EPA considers in assessing BAT are the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, and non-water quality environmental impacts, including energy requirements and such other factors as the Administrator deems appropriate. CWA section 304(b)(2)(B). The Agency retains considerable discretion in assigning the weight to be accorded these factors. *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011, 1045 (D.C. Cir. 1978).

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

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

3. Pretreatment Standards for Existing Sources (PSES)

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

4. Pretreatment Standards for New Sources (PSNS)

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

5. Best Management Practices (BMPs)

Section 304(e) of the CWA authorizes the Administrator to publish regulations, in addition to ELGs 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").

1.2.2 The National Pretreatment Program, 40 CFR 403

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

An IU is a nondomestic source of indirect discharge into a POTW, and in this rule is the dental discharger.[2] The Control Authority may be the POTW, the state, or EPA, depending on whether the POTW or the state is approved by EPA to administer the pretreatment program. The Control Authority is the POTW in cases where the POTW has an approved pretreatment program. The Control Authority is the state, where the POTW has not been approved to administer the pretreatment program, but the state has been approved. The Control Authority is EPA where neither the POTW nor the state have been approved to administer the pretreatment program. The Approval Authority is the state (Director) in an NPDES authorized state with an approved pretreatment program; or the EPA regional administrator in a non-NPDES authorized state or NPDES state without an approved state pretreatment program.

[2] EPA notes that the final rule is not determinative of the status of a dental discharger as an IU. In other words, dental dischargers are IUs in absence of this rule.

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

1.3 Regulatory History Of The Dental Category

This chapter presents a brief history of activities related to dental category rulemaking. Chapter 1.3.1 discusses EPA's Detailed Study of the Dental Category. Chapter 1.3.2 discusses the 2008 memorandum of understanding to reduce mercury discharges. Chapter 1.3.3 describes the American Dental Association's Best Management Practices and support of a national rulemaking. Chapter 1.3.4 describes the proposed rule for the dental category, and Chapter 1.3.5 describes existing state and local programs for dental discharges. Chapter 1.3.6 discusses the 2013 Minamata Convention on Mercury.

1.3.1 Detailed Study of the Dental Category

EPA first identified the dental industry for study in its review of the health services industry in the 2006 Effluent Guidelines Plan (71 FR 76644). EPA selected the industry based in part on public comments about discharges of mercury from dental offices and dental laboratories. EPA's study addressed the following questions:

- What are the current industry practices for disposing of dental mercury, to what extent are each of these practices applied, and what factors affect the use of these practices?
- What are the federal, state, or local requirements or guidance for disposal of dental mercury?
- How are Control Authorities currently limiting dental mercury discharges?
- Do POTWs report pass through or interference problems related to dental mercury discharges?

- What technologies are available (1) as alternatives to wastewater disposal and (2) to control discharges? How effective are these technologies?
- What BMPs are used as alternatives to wastewater disposal and/or to control discharges? How effective are these practices?
- What are the costs of the identified technologies and/or BMPs?

EPA documented its findings in the August 2008 technical report, *Health Services Industry Detailed Study: Dental Amalgam* (EPA-821-R-08-014).

1.3.2 2008 Memorandum of Understanding on Reducing Mercury Discharges

In December 2008, EPA signed a memorandum of understanding (MOU) with the American Dental Association (ADA) and the National Association of Clean Water Agencies (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. EPA did not evaluate the effectiveness of the MOU, rather EPA decided that National Pretreatment Standards for dental facilities would accomplish the goals of the MOU in a more predictable timeframe.

1.3.3 ADA Best Management Practices 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 (ADA, 2007).

In late 2010, ADA’s Board of Directors adopted nine principles upon which ADA supported National Pretreatment Standards for dental facilities (ADA, 2010).

1.3.4 Proposed Rule for the Dental Category

EPA published proposed pretreatment standards for the dental category on October 22, 2014 (79 FR 63258), and took public comment through February 20, 2015. During the public comment period, EPA received approximately 200 comments submitted to the Federal Data Management System (FDMS) Docket Number: EPA–HQ–OW–2014–0693. EPA also held a public hearing on November 10, 2014. Administrative burden was a concern of many of the commenters on the 2014 proposed rule, particularly from regulatory authorities responsible for oversight and enforcement of the new standard. Commenters also provided additional information on amalgam separators (e.g., costs, models, and design) as well as information on some other approaches to reduce pollutant discharges from dentists. Commenters also offered ways to improve and/or clarify the proposed pretreatment standards, including the proposed numerical efficiency and operation and maintenance requirements. See the *Effluent Limitations*

Guidelines and Standards for the Dental Category: EPA's Response to Public Comments (U.S. EPA, 2016a) for these comments and EPA's responses.

1.3.5 State and Local Programs

Currently, 12 states (Connecticut, Louisiana[3], Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New Mexico, New York, Rhode Island, Vermont, and Washington) have mandatory programs to reduce dental mercury discharges. Additionally, at least 18 localities (located in California, Colorado, Ohio, and Wisconsin) similarly have mandatory dental amalgam reduction pretreatment programs. EPA analyzed readily available information about these programs and found commonalities (U.S. EPA, 2016b). For example, all require the use of amalgam separators and most specify associated operating and maintenance requirements. The majority of these programs also require some type of best management practices, and at least a one-time compliance report to the regulating authority. See Chapters 6.3 and 6.4 of this document for more details on these programs.

1.3.6 Minamata Convention on Mercury

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

1.4 References

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ADA. 2010. ADA Principles to be used to Develop Mandatory Separator Pretreatment Rule. Washington, DC. October 29. DCN DA00137.

U.S. EPA. 2016a. *Effluent Limitations Guidelines and Standards for the Dental Category: EPA's Response to Public Comments*. Office of Water. Washington, DC. December. DCN DA00516.

U.S. EPA. 2016b. *Interaction of Mandatory State and Local Dental Amalgam Reduction Programs and the Dental Rule*. Memorandum to the Public Record for the Dental Category Final Rule. Office of Water. Washington, DC. December 6. DCN DA00524.

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

Chapter 2
Summary and Scope

The purpose of the dental category final rule is to set technology-based pretreatment standards to reduce discharges of mercury from dental offices to municipal sewage treatment plants, known as publicly owned treatment works (POTWs), in the United States. Across the U.S., 12 states and at least 18 localities have established mandatory programs to reduce discharges of mercury to POTWs. As a result of these efforts, along with outreach from the American Dental Association (ADA) to promote voluntary actions to reduce such discharges, approximately 40 percent of the dental offices subject to this rule have already installed amalgam separators. Amalgam separators greatly reduce the discharge of mercury-containing amalgam to POTWs. This rule will ensure that mercury discharges to POTWs are effectively controlled at dental offices that discharge wastewater to POTWs.

Many studies have been conducted to identify the sources of mercury entering POTWs. According to the 2002 Mercury Source Control and Pollution Prevention Program Evaluation prepared for the Association for Metropolitan Sewerage Agencies (AMSA), dental practices are the main source of mercury discharges to POTWs (Larry Walker Associates, 2002). A study funded by the ADA published in 2005 estimated that dental offices contributed more than 50 percent of mercury entering POTWs (Vandeven and McGinnis, 2005).[4] Mercury is discharged in the form of waste dental amalgam when dentists remove old amalgam fillings from cavities, and from excess amalgam waste when a dentist places a new amalgam filling. [5]

While dental offices are not a major contributor of mercury to the environment generally, dental offices are the main source of mercury discharges to POTWs. EPA estimates that across the United States, 5.1 tons of mercury and another 5.3 tons of other metals found in waste dental amalgam are collectively discharged into POTWs annually (U.S. EPA, 2016a). Mercury entering POTWs frequently partitions into the sludge, the solid material that remains after wastewater is treated. Mercury from waste amalgam therefore can make its way into the environment from the POTW through the incineration, landfilling, or land application of sludge or through surface water discharge. Once released into the aquatic environment, certain bacteria can change mercury into methylmercury, a highly toxic form of mercury that bioaccumulates in fish and shellfish. In the U.S., consumption of fish and shellfish is the main source of methylmercury exposure to humans. This chapter summarizes the final rule, its application, and subcategorization.

2.1 Summary Of The Final Rule

The final rule requires dental offices to control the discharge of mercury and other metals in dental amalgam to POTWs based on the best available technology or best available demonstrated control technology. Specifically, the requirements are based on the use of amalgam separators and best management practices recommended by the ADA. The BMPs are (1)

[4] EPA performs a similar calculation to estimate current mercury discharges from dental offices. See Chapter 11 of this document.

[5] Other filling types, such as composite fillings, do not contain mercury or other metals.

prohibiting the discharge of waste (or "scrap") amalgam and (2) prohibition of the use of line cleaners that are oxidizing or acidic and that have a pH higher than 8 or lower than 6. Amalgam separators are a practical, affordable and readily available technology for capturing mercury and other metals before they are discharged into sewers that drain to POTWs. The mercury collected by these separators can be recycled. This final rule also includes a provision to significantly reduce and streamline the oversight and reporting requirements in EPA's General Pretreatment Regulations that would otherwise apply as a result of this rulemaking. EPA expects that compliance with this final rule would reduce the transfer of metals to POTWs by 10.3 tons per year, almost half of which (5.1 tons) is mercury (U.S. EPA, 2016a). EPA estimates the annual cost of the final rule would be $59 to $61 million (U.S. EPA, 2016b).

The final rule requires dental offices to meet a performance standard – BMPs and the use of an amalgam separator(s) compliant with the 2008 International Organization for Standardization (ISO) 11143 standard (ISO, 2008), or the American National Standards Institute (ANSI)/ADA Specification 108 for Amalgam Separators (2009) with Technical Addendum (2011), (ANSI/ADA, 2009; ANSI/ADA, 2011), or subsequent versions so long as that version requires amalgam separators to achieve at least a 95% removal efficiency. ISO, a voluntary standard setting organization, established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam solids using specified test procedures in a laboratory setting. In order to meet the ISO standard, a separator must achieve 95 percent removal or greater of total solids. The standard also includes requirements for instructions on the use and operation and maintenance of amalgam separators (see Chapter 7.1.2). The final rule also includes a provision such that the performance standard can be met with the use of an amalgam removing technology other than an amalgam separator (equivalent device). EPA included this provision to incorporate future technologies that achieve comparable removals of pollutants from dental discharges as amalgam separators but that may not fall under the amalgam separator classification. Because the rule does not include a numerical limit, the performance standards also specify certain operation and maintenance requirements for the amalgam separator(s) or comparable device to ensure they are operated optimally.

In addition to installing one or more amalgam separators compliant with the ISO 11143 standard (or its equivalent) and implementing the required BMPs, the pretreatment standards specify certain operating and maintenance requirements for the amalgam separator. These requirements include: documented amalgam separator inspection as specified by the manufacturer's user manual to ensure the separator is performing properly and to confirm that all amalgam process wastewater is flowing through the amalgam retaining portion of the separator; replacement of the amalgam retaining unit of the device in accordance with the manufacturer's schedule or when the amalgam retaining unit has reached the maximum level, whichever comes first; repair/replacement as needed; and recycling/disposal of amalgam waste. Reporting requirements include a One-time Compliance Report.

The final rule allows dental offices to continue to operate amalgam separators installed prior to publication of this final rule for the equipment lifetime or ten years (whichever comes first), as long as the dental discharger complies with the other rule requirements including the specified BMPs, operation and maintenance, reporting, and recordkeeping requirements. Once the separator needs to be replaced or the ten-year period has ended, whichever comes first, dental offices will need to replace the amalgam separator with one that meets the requirements of the final rule.

Dental offices that do not place amalgam, and do not remove dental amalgam except in limited emergency or unplanned, unanticipated circumstances are exempt from any further requirements as long as they certify such in their One-time Compliance Report.

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

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

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

2.2 Applicability Of The Final Rule

Consistent with the proposal, dental offices that discharge to POTWs are within the scope of this final pretreatment rule.[6,7] EPA identified four dental offices that discharge wastewater directly to waters of the United States under a National Pollutant Discharge Elimination System (NPDES) permit (see Chapter 4.3). EPA solicited information in the proposal from the public on its preliminary finding that, with few exceptions, dental offices do not discharge wastewater directly to surface waters. EPA did not receive any comments containing data to contradict this finding. Therefore, EPA is not establishing any requirements for direct wastewater discharges from dental offices to surface waters at this time.

The final rule applies to wastewater discharges to POTWs from offices where the practice of dentistry is performed, including large institutions such as dental schools and clinics; permanent or temporary offices, home offices, and facilities; and including dental offices owned and operated by federal, state, or local governments including military bases. The final rule does not apply to wastewater discharges from dental offices where the practice of dentistry consists exclusively of one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics. As described in Chapter 4.2, these specialty practices are not expected to engage in the practice of amalgam placements (restorations) or removals, and are not expected to have any wastewater discharges containing dental amalgam.

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

2.3 Subcategorization

In developing effluent limitations guidelines and pretreatment standards, EPA may divide an industry category into groupings called subcategories to provide a method for addressing

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[6] The final rule does not apply to dental discharges to septic systems. This includes dental discharges to septic systems that are subsequently pumped out and transported to POTWs.

[7] The final rule does not apply to dental offices that collect all of their amalgam process wastewater and that transfer it to a privately owned treatment facility (also referred to as a centralized waste treatment facility or CWT). See § 441.10(e). As a point of clarification, dental offices (or a third party) that truck their amalgam wastewater to a POTW without first treating that wastewater at a CWT *are* dental dischargers subject to the rule.

variations among products, processes, and other factors, which result in distinctly different effluent characteristics. See *Texas Oil & Gas Ass'n. v. US EPA*, 161 F.3d 923, 939-40 (5th Cir. 1998). 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. Subcategorization, where warranted, ensures that each subcategory has a uniform set of ELGs that takes into account technology availability and economic achievability and other relevant factors unique to that subcategory.

This chapter presents information about factors EPA evaluated to determine whether subcategorization is warranted in the dental category. Chapter 2.3.1 describes the factors and Chapter 2.3.2 presents EPA's analyses of the factors.

2.3.1 Subcategorization Factors

The CWA requires EPA to consider a number of different factors when developing ELGs for a particular industry category (section 304(b)(2)(B), 33 U.S.C. 1314(b)(2)(B)). For best available control technology economically available (BAT), in addition to the technological availability and economic achievability, these factors are the age of the equipment and plants, the process employed, the engineering aspects of the application of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impacts (including energy requirements), and such other factors the Administrator deems appropriate.

2.3.2 Analysis of Subcategorization Factors

EPA assessed age, location, office size, office type, office configuration, and office type on the wastewaters generated at dental offices and the availability of technologies to manage those wastewaters. EPA determined none of these factors warrants different standards. The following chapters summarize the analyses performed as part of the subcategorization evaluation.

2.3.2.1 Age of dental office

EPA analyzed the age of dental offices included in the scope of the rule and determined that the age of the office by itself does not affect the wastewater characteristics or the dental processes in place. By dental processes, EPA means those procedures at the dental office that result in process wastewater that contains dental amalgam. For purposes of this analysis, EPA considers dental offices that conduct placements or restorations of dental amalgam, and/or that perform removals of dental amalgam, as dental processes. The age of the dental office does not affect the characteristics of the amalgam process wastewater generated by these dental processes. EPA reviewed the compliance rates in the states and localities that already have dental amalgam programs, and did not identify where age of the dental office was a factor in the ability of the dental office to install and operate an amalgam separator (see Chapter 6). Finally, the age of the office does not influence whether the BMPs required under this rule (waste amalgam must not be discharged to a POTW, and a prohibition on cleaning the dental lines with oxidizing or acidic cleaners; see 441.40(b)), or whether different BMPs, are warranted.

2.3.2.2 Geographic location

EPA analyzed the geographic location of dental offices included in the scope of the rule. Dental offices are located in all 50 states (see Chapter 4). EPA determined that the geographic location by itself does not affect the wastewater characteristics, the processes in place, or the ability to install and operate the treatment technologies evaluated as part of the final rule. EPA reviewed the compliance rates in the states and localities that already have dental amalgam programs, and did not identify where age of the dental office was a factor in the ability of the dental office to install and operate an amalgam separator (see Chapter 6). EPA found that dental offices all over the U.S. have installed amalgam separators. The BMPs have been required in several States and localities with dental amalgam programs, and some dentists have voluntarily adopted these BMPs as part of their adopting ADA's 9 Principles. Therefore, different requirements are not warranted.

2.3.2.3 Size of office

EPA analyzed the size of the dental office (*i.e.*, number of chairs) and determined that, while a dental office with multiple chairs in which amalgam may be placed or removed may have higher pollutant discharges (mass and volume) than an office with a single chair, the size of the dental office by itself does not affect the ability to install the treatment technologies evaluated as part of the final rule. Additionally, while the size of the dental office likely influences the volume of the amalgam process wastewater, this also does not warrant different requirements for the following reasons. EPA identified 26 amalgam separator models that meet the requirements of the final rule. Many of the models are scaled to the size of the office. EPA also found that very large offices (institutions and military bases) were able to scale up amalgam separators or have custom amalgam separator units designed for the large application. Some of these large offices have already adopted the two BMPs identified for the final rule, such as where the BMPs are already required in States and localities with dental amalgam programs, and some dentists have voluntarily adopted these BMPs as part of their adopting ADA's 9 Principles. As a result of its evaluation, EPA concludes that it would not be appropriate to apply different standards based on size of the dental office. The requirements do not include a size threshold because the technology(ies) is readily scaled to the size of the dental office.

2.3.3 <u>Office Configuration</u>

EPA has identified dental offices all over the country that perform dental processes, and has only identified one situation where the process wastewaters may vary: the use of dry pumps instead of wet vacuums. EPA does not have any data on the frequency of the use of dry pumps, but does note it is a relatively new practice. EPA finds that this is not a basis for subcategorization for several reasons. First, if the dental office does not generate any amalgam process wastewater, the rule would not apply. Second, if the office still generates amalgam process wastewater due to cuspidors, sinks, collection equipment, washing of dental equipment, and other office equipment used for amalgam process wastewater, then the rule would apply and the technology basis for the rule (e.g. amalgam separators) would still be BAT. The use of dry pumps does not change the availability or need of the two BMPs for dental amalgam. Therefore, office configuration does not warrant different requirements.

2.3.3.1 Specialty Type

EPA analyzed the types of dental offices (*e.g.* specialty practices) and determined that some dental specialties do not place or remove amalgam and are not expected to have any wastewater discharges containing dental amalgam. The final rule does not apply to them.

2.4 References

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Chapter 3
Data Collection Activities

EPA collected data from a variety of sources for the final dental category rulemaking, including the Health Services Industry Detailed Study, stakeholder discussions, amalgam separator manufacturer contacts, and the United States Air Force study on commonly used amalgam separator systems. This chapter includes a description of each data source; Chapter 4 through Chapter 14 and Chapter 16 of this document include summaries and analyses of the data collected by EPA. EPA used data from these sources to develop a profile of the industry; describe dental mercury sources and waste characteristics; describe the environmental impacts of mercury; identify state and local programs to reduce mercury discharges from dental offices; characterize the effectiveness and costs of amalgam separators and best management practices (BMPs); and develop pollutant discharge loadings estimates with and without control technologies.

3.1 HEALTH SERVICES INDUSTRY DETAILED STUDY

EPA first identified the dental industry for study in its 2006 Effluent Guidelines Plan (71 FR 76644) as part of the health services industry. In 2008, EPA published its results from the detailed study in the technical report, *Health Services Industry Detailed Study: Dental Amalgam* (U.S. EPA, 2008). For that report, EPA compiled and summarized information on mercury discharges from dental offices, BMPs, and amalgam separators. Regarding amalgam separators, EPA examined their frequency of use, their effectiveness in reducing mercury discharges to publicly owned treatment works (POTWs), and the capital and annual costs of their installation and operation. The detailed study report also includes a preliminary industry profile that provides the number of dental offices, the number of small businesses, discharge information, financial characteristics of the industry, and a description of the national, state, and local mandatory and voluntary programs to reduce mercury wastewater discharges from dental offices.

3.2 EPA STRATEGIES TO REDUCE MERCURY DISCHARGES

Before developing the final pretreatment standards, EPA, including its regional offices, worked closely with states and communities to develop strategies for reducing mercury discharges, including discharges from dental offices. For example, EPA's Environmental Technology Verification Program studied amalgam separators to determine effectiveness (Grubbs, 2003). In addition, EPA regional offices participated in seminars and workshops with local organizations and other federal agencies to evaluate risks, develop recommendations, disseminate information, and communicate with the public regarding a wide range of mercury-associated issues. For example, EPA Region 4 participated in the Project Team on Consumption Advisories for Mercury in Gulf of Mexico Marine Fish. In addition, EPA Regions 5 and 8, as well as EPA Headquarters, participated in the activities listed below to limit mercury discharge from dental offices.

- *Region 5*. EPA and Environment Canada, working through the Great Lakes Bi-national Toxics Strategy, created a Mercury Workgroup that promoted activities to reduce mercury releases to the Great Lakes Basin. This Workgroup included representative states, environmental organizations, and the Council of Great Lakes Industries. The Workgroup's review of mercury releases in the Great Lakes area focused on air emissions. As a result, the Workgroup did not collect trend data on mercury releases to water. The Workgroup reviewed information on BMPs and successful voluntary and regulatory approaches used in state and local programs, including dental amalgam reduction programs in King County, WA; Toronto, ON; Duluth, MN; and Cleveland, OH (Cain and Krauel, 2004). The Workgroup did not quantify reductions in mercury use or reductions in wastewater discharges to POTWs.

- *Region 8*. EPA Region 8 developed a draft Mercury Control Strategy to help POTWs control mercury pollution problems from commercial and smaller industrial users, including dental offices. This draft Strategy included detailed information on the development of BMPs, amalgam separators, and other removal and filtration devices, as well as other background information regarding dental amalgam control approaches (U.S. EPA, 2005).

3.3 LITERATURE REVIEW

EPA reviewed literature and collected data on various aspects of the dental industry, amalgam separators, and mercury discharges, including:

- Current, relevant technical publications that describe the sources and generation of mercury wastes at dental offices and the discharge of mercury and other amalgam filling metals (i.e., copper, silver, tin, and zinc) to POTWs.

- Current information on possible treatment solutions (i.e., amalgam separators) for dental offices to reduce mercury in the wastewater and their effectiveness.

- Current implementation costs for technologies to reduce mercury and other metal discharges at dental offices.

3.4 MEETINGS WITH STAKEHOLDERS

EPA participated in several meetings with stakeholders including the Environmental Council of the States (ECOS), Association of Clean Water Act Administrators (ACWA), environmental organizations, the American Dental Association (ADA), the National Association of Clean Water Agencies (NACWA), and various environmental organizations. Chapters 3.4.1 through 3.4.5 summarize information collected during these meetings.[8]

3.4.1 Environmental Council of the States

EPA participated in several meetings with the Quicksilver Caucus (QSC) of the Environmental Council of the States. From QSC, EPA collected information on implementing mandatory amalgam separator programs at the state level, mandatory program language, and

[8] EPA documented meetings conducted after publication of the proposed rule in a memorandum to the public record entitled "Meetings Held Between EPA and Stakeholders after the Proposed Rule" (U.S. EPA, 2016).

compliance reporting and monitoring. QSC also provided EPA with information on efficiency standards for amalgam separators (ECOS, 2010).

3.4.2 Association of Clean Water Act Administrators

EPA participated in several meetings with the Association of Clean Water Act Administrators. From ACWA, EPA collected information on existing state dental amalgam reduction programs including lessons they learned while implementing these programs.

3.4.3 Environmental Organizations

EPA met with a coalition of environmental organizations, led by The Environmental Law and Policy Center and the National Resources Defense Council (NRDC). In spring 2011, the coalition submitted a letter listing its suggested BMPs for a dental category rulemaking (Wu, 2011). Meetings between EPA and the coalition of environmental organizations and NRDC focused on identifying the environmental impacts of dental amalgam discharges and ways to reduce them.

3.4.4 American Dental Association (ADA)

EPA met with ADA multiple times during this rulemaking. Among other things, ADA provided data to EPA on their BMPs, the nine principles upon which ADA supports national pretreatment standards for dental facilities, the number of specialty offices in the industry, the geographic distribution of dental offices, financial characteristics of the industry, information on the use of dental amalgam alternatives, and operating characteristics of the industry.

3.4.5 National Association of Clean Water Agencies (NACWA)

EPA met with NACWA multiple times to discuss the impact of pretreatment standards on POTWs. NACWA provided EPA information on its members' experiences with handling mercury wastes from dental offices, and implementing pretreatment standards for other industries. NACWA also provided EPA with information on the burden to permitting authorities of implementing a dental amalgam pretreatment standard under the existing requirements in Part 403.

3.5 AMALGAM SEPARATOR MANUFACTURERS (VENDOR CONTACTS)

EPA met with, or participated in calls with, representatives of multiple amalgam separator manufacturers. The purpose of the meetings was to gather information on the following issues:

- How amalgam separators work, limitations of the technology, and system capacity;
- Treatment technology effectiveness;
- Installation, operation, and maintenance requirements and equipment lifetime;
- Capital costs and operating and maintenance costs;
- Manufacturers' distribution methods;

- Amalgam disposal; and
- Installation trends.

3.6 AIR FORCE STUDY

In anticipation of the dental category rulemaking, the United States Air Force Dental Evaluation and Consultation Service compiled a synopsis of commonly used amalgam separator systems (U.S. Air Force, 2011). The purpose of this synopsis was to introduce dental clinics to available amalgam separation system options. The Dental Evaluation and Consultation Service focused on amalgam separators that are marketed directly to dentists (not necessarily all systems available). The study includes tables for dentists to select the system that best meets their needs, as well as highlighting key points, questions, and items for dentists to consider before purchasing an amalgam separator. The study recommends that clinics actively involve their office managers and biomedical engineering technicians in the purchasing decision to ensure compatibility of the amalgam separator with existing office features, proper installation, future maintenance requirements, and proper disposal of the waste.

For each system, the synopsis describes whether the separator is compliant with the ISO 11143 standard, installation requirements, design capacity, maintenance requirements, recycling services available from the manufacturer, size, price, and warranty details. EPA incorporated these data into the technology cost analysis.

3.7 REFERENCES

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Chapter 4
Profile of Dental Industry

The industry category that would be affected by the dental category rulemaking is Offices of Dentists (NAICS[9] 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 Management Organization (HMO) medical centers. They can provide either comprehensive preventive, cosmetic, or emergency care, or specialize in a single field of dentistry. EPA used data from the U.S. Census, EPA's Toxic Release Inventory (TRI), and discharge monitoring reports (DMR)[10] to estimate the number of dental offices and to understand how they discharge their wastewater.

TRI and the U.S. Census classify industries by NAICS codes, while DMR classifies industries by Standard Industrial Classification (SIC) codes. There is a 100 percent correlation between NAICS and SIC codes for the dental industry. Dental offices fall under NAICS 621210 (SIC Code 8021), with the definition:

> "This industry comprises establishments of health practitioners having the degree of D.M.D. (Doctor of Dental Medicine), D.D.S. (Doctor of Dental Surgery), or D.D.Sc. (Doctor of Dental Science) primarily engaged in the independent practice of general or specialized dentistry or dental surgery. These practitioners operate private or group practices in their own offices (e.g., centers, clinics) or in the facilities of others, such as hospitals or health management organization (HMO) medical centers. They can provide either comprehensive preventive, cosmetic, or emergency care, or specialize in a single field of dentistry."

4.1 Number Of Dental Offices

EPA's main source of information for the number of dental offices is the 2012 Economic Census, which reported that there were 133,221 U.S. dental offices. Table 4-1 provides a comprehensive listing of the dental offices by state for NAICS 621210 (Dental Offices). The number of dental offices has increased approximately one percent each year. Table 4-2 shows the industry changes over time. The financial profile of the dental industry is included in Chapter 10 of this document.

In addition to dental offices, dentistry can be performed at larger institutional dental offices (e.g., clinics or dental schools). These dental offices are not included in the 2012 Economic Census data. EPA estimates that in addition to the 133,221 dental offices identified from the Economic Census, there are 350 military clinics and 65 dental schools (U.S. EPA, 2016a).

[9] North American Industry Classification System.

[10] The DMR data are from EPA's Integrated Compliance Information System-National Pollutant Discharge Elimination System (NPDES) database.

Table 4-1. Number of Dental Offices by State (2012)

State	NAICS 621210: Dental Offices
Alabama	1,492
Alaska	311
Arizona	2,695
Arkansas	1,000
California	21,157
Colorado	2,791
Connecticut	1,780
Delaware	251
District of Columbia	334
Florida	7,770
Georgia	3,445
Hawaii	658
Idaho	784
Illinois	6,012
Indiana	2,376
Iowa	1,058
Kansas	1,068
Kentucky	1,567
Louisiana	1,599
Maine	479
Maryland	2,638
Massachusetts	3,196
Michigan	4,282
Minnesota	1,991
Mississippi	884
Missouri	2,113
Montana	452
Nebraska	804
Nevada	1,096
New Hampshire	611
New Jersey	4,792
New Mexico	691
New York	9,264
North Carolina	3,154
North Dakota	267
Ohio	4,323
Oklahoma	1,391
Oregon	1,934
Pennsylvania	5,200

Table 4-1. Number of Dental Offices by State (2012)

State	NAICS 621210: Dental Offices
Rhode Island	395
South Carolina	1,539
South Dakota	299
Tennessee	2,204
Texas	9,446
Utah	1,664
Vermont	260
Virginia	3,243
Washington	3,558
West Virginia	552
Wisconsin	2,119
Wyoming	232
Total U.S.	**133,221**

Source: U.S. Census Bureau, 2012.

Table 4-2. Growth in Number of Dental Offices (1997 to 2012)

NAICS Code	SIC Code	Number of Offices in 1997	Number of Offices in 2002	Number of Offices in 2005	Number of Offices in 2007	Number of Offices in 2012
621210: Offices of Dentists	8021: Offices and Clinics of Dentists	114,178	118,305	122,918	127,057	133,221

Sources: Johnston, 2005; U.S. Census Bureau, 2007a and 2007b; U.S. Census Bureau, 2012.

4.2 Specialty Practices At Dental Offices

Dentistry includes the evaluation, diagnosis, prevention, and treatment of diseases, disorders, and conditions of the oral cavity, maxillofacial area, and the adjacent and associated structures. Services provided include nonsurgical and surgical or related procedures. Most dental offices fall under the category of general dentistry. In addition to a general practice, dentists may specialize in other areas. Dentists who typically place or remove dental amalgam are either general dentists or specialize in pediatric dentistry. The nine areas of dentistry that EPA specifically evaluated for inclusion within the pretreatment standards include the following (ADA, 2011):

- General dentistry—practice provides primary and comprehensive preventive and therapeutic oral health care for patients.
- Pediatric dentistry—practice provides general dentistry services (i.e., primary and comprehensive preventive and therapeutic oral health care) for age-specific group (i.e., infants and children through adolescence).

- Endodontics—practice encompasses the basic and clinical sciences including biology of the normal teeth (pulp) and diseases/injuries of the teeth and associated condition of the root.
- Oral and maxillofacial pathology—practice focuses on diseases affecting the oral and maxillofacial regions.
- Oral and maxillofacial radiology—discipline concerned with the production and interpretation of images and data produced for the diagnosis and management of diseases, disorders, and conditions of the oral and maxillofacial region.
- Oral and maxillofacial surgery—specialty includes the diagnosis, surgical and adjunctive treatment of diseases, injuries, and defects involving both the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial region.
- Orthodontics and dentofacial orthopedics—specialty includes the diagnosis, prevention, interception, and correction of malocclusion (i.e., misalignment of teeth), as well as neuromuscular and skeletal abnormalities of orofacial structures.
- Periodontics—practice focuses on diseases of the supporting and surrounding tissues of the teeth or their substitutes.
- Prosthodontics—specialty service for patients with clinical conditions associated with missing or deficient teeth and/or oral and maxillofacial tissues using biocompatible substitutes.

Of the specialty practices listed above (i.e., all practices except general and pediatric dentistry), EPA expects only endodontic and prosthodontic offices to place or remove amalgam. EPA is not including wastewater discharges from dental offices where the practice does not typically place or remove dental amalgam.

ADA compiled data on the supply of dentists from 2001 through 2015 by type practice, including general practice and nine specialty practices (ADA, 2016). Of the 195,722 dentists practicing in 2015, 154,719 dentists are in general practices (79 percent) and 41,003 dentists are in specialty practices (21 percent). There are 16,163 dental offices that practice pediatric dentistry, endodontics, or prosthodontics (39 percent of specialty practices). Therefore, EPA estimates that over 116,000 dental offices[11] would be subject to the final dental category rulemaking.

4.3 Discharge Information

EPA currently lacks a central database on reported discharges from dental offices. Often, EPA looks to information in TRI and DMR databases to gather information on industrial dischargers. However, no dental office (NAICS Code 621210) reports to TRI as they are not required to do so. Based on information contained in EPA's Envirofacts PCS-Integrated Compliance Information System[12] database, EPA identified four dental offices that have National

[11] In addition to dental offices, large, institutional offices are also subject to the final rule. EPA estimates there are 415 of these large, institutional offices.

[12] Permit Compliance System- Integrated Compliance Information System.

Pollutant Discharge Elimination System (NPDES) permits in 2016. The dental offices were classified as minor dischargers. Of these, none of the offices reported discharge information in the database. Table 4-3 lists the dental offices with NPDES permits in the PCS-Integrated Compliance Information System database.

Table 4-3. Dental Offices with NPDES Permits in Integrated Compliance Information System -NPDES[a]

NAICS (SIC)	NPDES ID	Office Name	Location
621210: Dental Offices (8021: Dental Offices)	COR03N267	Perfect Teeth Commerce City	Commerce City, CO
	COR03Q060	Coal Creek Oral Surgery	Lafayette, CO
	MDG766085	Magothy Marina[b]	Annapolis, MD
	MI0053902	University of Michigan[b]	Ann Arbor, MI

Source: U.S. EPA, 2016b.

a – The Integrated Compliance Information System-NPDES database includes two additional NPDES permits in Michigan but not for dental offices (two localities); EPA assumed the dental offices in the localities are discharging indirectly to POTWs. The database also identified 17 NPDES permits in Louisiana; EPA confirmed that Louisiana used the general permit identification numbers to identify dental offices that use an amalgam separator. EPA confirmed the 17 facilities are indirect dischargers (U.S. EPA, 2016c).

b – Dental offices may be included in combined discharges to surface waters.

The lack of discharge information is consistent with EPA's 2007 and 2005 reviews of the dental industry. These reviews indicate that nearly all dental offices are indirect dischargers (Johnston, 2005; U.S. EPA, 2008).

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Chapter 5
Dental Amalgam Waste, Pollutants of Concern, and POTW Pass Through

This chapter discusses the sources of amalgam waste from dental offices and describes a typical office configuration. This chapter also focuses on the pollutants of concern for amalgam waste and the pass through of these pollutants at publicly owned treatment works (POTWs).

5.1 Sources Of Dental Amalgam In Wastewater From Dental Offices

Dental amalgam used in dental offices consists of approximately 49 percent mercury, by weight, mixed with a powder of silver, tin, copper, and zinc, and small amounts of indium or palladium. The liquid mercury and metal powder mixture are often supplied in capsules, in which they are kept separate until the dentist is ready to complete a restoration. When the dentist triturates (mixes) the mercury and powder, the mercury dissolves the powdered metals and a series of intermetallic compounds (e.g., Ag_3Sn, Ag_2Hg_3, Sn_8Hg) are formed (Vandewall, 2007).

Amalgam discharges generally occur in the course of two dental office activities. The first activity is patient treatment, such as during the placement or removal of a filling. When filling a cavity, dentists overfill the tooth and then carve the filling into proper shape (Columbia University, 2005). The dentist then typically rinses the excess amalgam into a chair-side drain with a cuspidor or suctions it from the patient’s mouth with a vacuum system. Dentists also remove old cavity restorations that are worn or damaged. Removed restorations are also rinsed into the chair-side drain or suctioned out of the patient’s mouth. The second activity where amalgam discharges occur is 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 also can result in discharge of dental amalgam mercury.

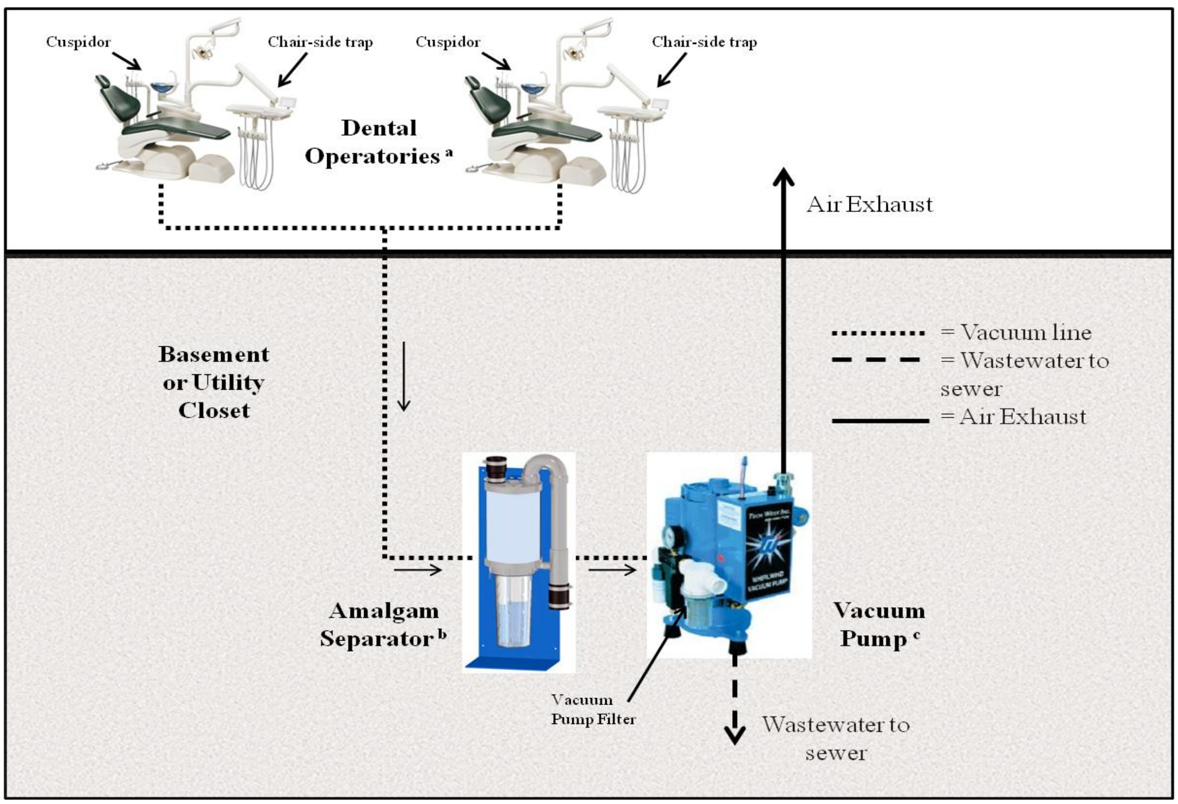
Dental amalgam traditionally has been used as a restorative material for cavities because the malleability of newly mixed amalgam makes it easy to place into cavities and because of its durability over time. The use of dental amalgam has decreased steadily since the late 1970s as alternative materials such as composite resins and glass ionomers have become more widely available. Some dental offices have also elected not to remove amalgam restorations.

Estimates show that placements of dental amalgam have decreased on average by about 2 to 3 percent per year (74 FR 38686). However, even with decreasing placements of dental amalgam, removals of dental amalgam already placed in patient’s mouths will continue into the foreseeable future. Available data shows removals comprise the largest portion of dental amalgam discharges from dental offices. This is further described in Chapter 11.

Another source of dental amalgam in wastewater is from the flushing of dental unit wastewater lines and wastewater plumbing. Dental offices use disinfectants or line cleaners to reduce odors, remove solid waste particles and biofilms in the lines, and to maintain low microbial counts in dental unit water. When dental offices use oxidizing or acidic lines cleaners, such as bleach, chlorine, iodine and peroxide, mercury can be released from the amalgam waste that has collected in the system (e.g., wastewater and plumbing lines, chair-side traps, vacuum pump filters, and amalgam separators) (Batchu et. al., 2006). Oxidizing line cleaners can also solubilize elemental mercury bound to the amalgam.

5.2 DENTAL OFFICE CONFIGURATION

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. A cuspidor may or may not be part of the plumbing configuration at a dental office. The chair-side traps and vacuum pump filters remove approximately 78 percent of dental amalgam particles from the wastewater stream (Vandeven and McGinnis, 2005). Offices with multiple chairs typically share the vacuum lines between chairs. Accordingly, this limits the locations for installation of control and treatment technologies. Dental offices may install controls 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. Figure 5-1 displays a typical plumbing configuration in a dental office and includes an amalgam separator installed at a central location upstream of the vacuum pump. In this configuration, wastewater in the vacuum line goes through the amalgam separator, and the cuspidor drain is connected to the central vacuum line (Dube, 2010; McManus and Fan, 2003).



[a] (Flight Dental Systems, 2006)
[b] (Dental Equipment & Repair, 2008)
[c] (Dental Classifieds, 2011)
Sources: Dube, 2010; McManus and Fan, 2003.

Figure 5-1. Typical Amalgam Separator Plumbing Configuration in a Dental Office

Physical office and building configurations may pose additional installation considerations, such as space limitations in the absence of a basement, 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.

5.3 POLLUTANTS OF CONCERN AND PASS THROUGH

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

5.3.1 POTW Pass Through Analysis

Generally, in determining whether pollutants pass through a POTW when considering the establishment of categorical pretreatment standards, EPA compares the median percentage of the pollutant removed by POTWs achieving secondary treatment with the median percentage of the pollutant removed by facilities meeting BAT effluent limitations. EPA deems a pollutant to pass through a POTW when the percentage removed by POTWs is less than the percentage removed by direct dischargers complying with BPT[13]/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 the final rule for the dental category, where EPA is only developing pretreatment standards, EPA compares the POTW removals with removals achieved by indirect dischargers using the technology that otherwise satisfies the BAT factors.

Historically, EPA’s primary source of POTW removal data is its 1982 “Fate of Priority Pollutants in Publicly Owned Treatment Works” (also known as the 50 POTW Study). This well documented study presents data on the performance of 50 POTWs achieving secondary treatment in removing toxic pollutants. As part of the development of ELGs for the Centralized Waste Treatment (CWT) Industry promulgated in December 2000, EPA developed and documented a methodology, including data editing criteria, to calculate POTW percent removals for various toxic pollutants from the data collected in the study (U.S. EPA, 2000). EPA provided the opportunity for public comment on the percent removal methodology and the resulting percent removals in the CWT proposal. EPA similarly used and presented this methodology and data in subsequent ELG proposals and final rules.

As part of this methodology, EPA edited the data to minimize the possibility that low POTW removals might simply reflect low influent concentrations instead of treatment effectiveness:

[13] Best Practicable Control Technology Currently Available.

1. Substitute the standardized pollutant-specific minimum analytical detection limit (ML) for values reported as "not detected," "trace," "less than (followed by a number)," or a number less than the ML.

2. Retain pollutant influent and corresponding effluent values if the average pollutant influent level is greater than or equal to 10 times the pollutant ML.

3. If none of the average pollutant influent concentrations are at least 10 times the pollutant ML, then retain average influent values greater than or equal to two times the pollutant ML along with corresponding effluent data.

For each POTW that had data pairs that passed the editing criteria, EPA calculated its percent removal for each pollutant based on its average influent and average effluent values. The national POTW percent removal for each pollutant is the median value of all the POTW pollutant-specific percent removals.

The 50 POTW Study measured pollutant reductions on the basis of total metals. Total metals include particulate (suspended) and dissolved (soluble) forms of the metal. While mercury is present in dental amalgam in both the particulate and dissolved form, the vast majority (>99.6 percent) is particulate (Stone, 2004). While EPA does not have information on the distribution of the other metals present in dental amalgam, EPA reasonably assumed the same distribution for the other metals. Because secondary treatment technologies are not designed to remove dissolved metals, for purposes of this pass-through analysis, EPA assumes dissolved metals are not removed by POTWs and that the percent reductions for POTWs represent particulate (Metcalf & Eddy, 2003). Therefore, EPA used the 50 POTW Study percent removals to represent particulate[14] reductions. For the pollutants of concern, POTWs remove the following percentages from wastewater prior to discharge (U.S. EPA, 1982):

- 90.2 percent of mercury
- 88.3 percent of silver;
- 42.6 percent of tin;
- 84.2 percent of copper; and
- 79.1 percent of zinc.

EPA received data from targeted studies performed by NACWA that indicate a POTW can remove as much as 95 percent of total mercury (NACWA, 2007) and POTW performance data from a nationwide voluntary survey of NACWA members with a calculated three-year average removal efficiency[15] of 94 percent (U.S. EPA, 2016a). However, EPA finds these data

[14] Particulates are specified here because data shows a small portion of mercury from dental amalgam is in dissolved form. This introduces a small but negligible margin of error because: the vast majority (>99.6 percent) of total mercury is particulate mercury; amalgam separators are not typically designed for removal of dissolved mercury; the 2008 ISO 11143 testing protocol is for dental amalgam solids removal; and because secondary treatment at POTWs are not designed for dissolved mercury removal. However, to be more succinct, EPA refers to mercury removal by amalgam separators as removal of particulate mercury.

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

are not appropriate for replacing the 50 POTW data for a number of reasons; see Chapter 16 for further discussion of these data. Consequently, EPA found that data from the 50 POTW Study continues to represent the best data available to determine the percent removed nationwide by well operated POTWs employing secondary treatment.

To determine the median percent removal of mercury and other pollutants of concern by amalgam separators, EPA collected information on the efficacy of existing separators. EPA excluded those separators that did not meet the 2008 ISO 11143 standards. Amalgam separator efficiencies are measured as a percent reduction in mass, reflecting the dental amalgam particulates collected by the device. EPA determined the median percent removal of particulates by amalgam separators that meet the 2008 ISO 11143 standards is 99.3 percent (U.S. EPA, 2016b).

As discussed above, for the final rule, EPA maintained a POTW removal rate of 90.2 percent of total mercury for its nationwide pass-through analysis. The median percent removal of particulates by amalgam separators that meet the 2008 ISO standards is 99.3 percent. Because the median percent removal of amalgam separators exceeds the median percent removal of well-operated POTWs employing secondary treatment for mercury, EPA determines that mercury passes through. (Even if EPA were to use the data as reported by NACWA, the 94 percent removal efficiency is still less than the 99.3 percent removal efficiency of amalgam separators compliant with the 2008 ISO 11143 standards.) Similarly, because the median percent removal of amalgam separators exceeds the median percent removal of well-operated POTWs employing secondary treatment for the other pollutants of concern, EPA determines that these metals contained in dental amalgam (i.e., silver, tin, copper, and zinc), also pass through.

5.4 References

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Chapter 6
Current National, State, and Local Dental Mercury Reduction Programs

National, state, and local programs have reduced discharges of dental mercury to publicly owned treatment works (POTWs). National programs include the 2008 Memorandum of Understanding (MOU) between EPA, the American Dental Association (ADA), and the National Association of Clean Water Agencies (NACWA) (see Chapter 1.3.2) and best management practices (BMP) guidance from ADA. Currently, 12 states have established mandatory state-wide programs to control mercury discharges from dental offices. EPA also reviewed requirements for 18 local mandatory programs in four additional states. This chapter includes the following subchapters:

- Chapter 6.1 discusses national dental amalgam requirements.
- Chapter 6.2 describes national dental amalgam guidance.
- Chapter 6.3 summarizes state programs.
- Chapter 6.4 summarizes local programs.
- Chapter 6.5 presents voluntary programs.

6.1 National Dental Amalgam Requirements

Federal agencies that have established regulations for dental amalgam include the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA). Both federal regulations, however, focus on aspects of dental amalgam related to employee and consumer exposure and do not address wastewater discharges to POTWs. EPA regulates the disposal of mercury-containing waste under the Resource Conservation and Recovery Act (RCRA).

6.1.1 Resource Conservation and Recovery Act (RCRA)

A mercury-containing waste can be considered hazardous in two ways: (1) as a listed waste; or (2) as a characteristic waste.[16, 17] A waste is defined as a characteristic hazardous waste if it exhibits the toxicity characteristics for mercury, defined as containing enough mercury to exceed the regulatory threshold of 0.2 milligrams per liter (mg/L), or 0.2 parts per million (ppm), when subjected to a specific leach test known as the TCLP (Toxicity Characteristic Leaching Procedure; see 40 CFR 261.24). Persons who generate hazardous waste, such as a waste that exhibits the hazardous characteristics for mercury, are subject to specific requirements for the proper management and disposal of that waste. The federal RCRA regulatory requirements differ depending upon the total amount of hazardous waste a site generates per month. Most dental practices generate less than 100 kilograms of non-acute hazardous waste per month and less than

[16] There are also some source-specific hazardous wastes that are listed due to mercury; however, dental amalgam wastes are not listed in the hazardous-waste regulations at 40 CFR 261 Subpart D.

[17] Elemental mercury found in dental amalgam is a non-acute hazardous waste. Unused elemental mercury being discarded would be a listed hazardous waste (waste code U151).

1 kilogram of acute hazardous waste per month. Such facilities are therefore classified as "Very Small Quantity Generators" (VSQGs). VSQGs are not subject to most of the RCRA hazardous waste requirements, but do have restrictions on their disposal (see 40 CFR 262.14). Most states implement the RCRA program, and many states have additional requirements for the handling of mercury, including waste dental amalgam. Therefore, the requirements for handling mercury waste and dental amalgam waste can vary from state to state. EPA's compliance assistance center website provides links to state hazardous waste requirements (https://www.epa.gov/compliance/compliance-assistance-centers). Chapter 6.3 provides details on mandatory state programs for managing dental amalgam waste.

The Agency encourages the legitimate recycling of hazardous wastes when possible. Scrap dental amalgam contains both mercury and silver, and recovery of its silver value may be cost effective. Also, for generators of more than 100 kg hazardous waste per month, scrap amalgam can be recycled under reduced requirements by following the precious metal recovery regulations at 40 CFR 266.70. Further, waste from amalgam separators may be considered sludge under RCRA. Characteristic sludges are not solid or hazardous wastes when legitimately reclaimed. Likewise, any unused amalgam would be considered a commercial chemical product (CCP). CCPs also are not solid or hazardous wastes when legitimately reclaimed.

6.1.2 Occupational Safety and Health Administration

OSHA's authority regarding dental amalgam is limited to employee exposure resulting from handling or use of hazardous chemicals in the workplace. Dental amalgam is considered non-hazardous to consumers who receive dental restorations because the amalgam is considered benign once it is installed. However, workers handling amalgam have a greater potential for exposure than consumers, because dental workers handle liquid mercury while they prepare mercury amalgam restorations. For that reason, dental amalgam is classified as a hazardous chemical under OSHA's Hazard Communication Standard. Workers who handle amalgam alloy are entitled to protection under this standard, including the receipt of training and hazard information. OSHA's focus on dental amalgam is unrelated to the disposal or discharge of spent amalgam (OSHA, 1997).

6.1.3 Food and Drug Administration

FDA regulates dental amalgam under the Federal Food, Drug, and Cosmetic Act (FFDCA). The FFDCA classifies dental mercury as a Class I medical device and amalgam alloy as a Class II medical device (see Title 21, *Code of Federal Regulations*, sections 872.3700 and 872.3050). Class I medical devices are subject to extensive safety regulations for use. Class II medical devices are subject to additional special controls for use (Anderson, 2007). FDA and the Centers for Disease Control focus on the health risks of amalgams to dentists, dental workers, and patients, rather than on the disposal or discharge of spent amalgam (FDA, 2008).

6.2 National Dental Amalgam Guidance

The ADA has developed several programs to reduce dental mercury being discharged from dental offices. Programs include development of best management practices, a list of nine principles, and creation of an amalgam recovery program.

6.2.1 ADA Best Management Practices

The most widely known national voluntary program for reducing dental amalgam releases to the environment is the "Best Management Practices for Amalgam Waste" developed and approved by the ADA Board of Trustees. ADA first published this program in January 2003 and updated it in 2007 to include amalgam separators. The ADA-defined BMPs are recognized as the industry standard; all state and local voluntary programs are based on or derived from the guidance provided in the ADA BMPs.

ADA provides guidance documents for its members and the general public for the proper management, recycling, and disposal of amalgam waste. ADA also provides advice for successful integration of BMPs into dental offices, a directory of national dental amalgam waste recyclers, recommendations for safe preparation and placement of amalgam restorations, safety information for managing mercury spills, and advice on the purchase, installation, and operation of amalgam separators (ADA, 2007). Table 6-1 lists the ADA BMPs for dental amalgam.

Table 6-1. ADA BMPs for Dental Amalgam

Focus	Best Management Practice
General	Recycle amalgam waste as much as possible. Do not flush amalgam waste down the drain or toilet. Use line cleaners that minimize the dissolution of amalgam. Do not use bleach or chlorine-containing cleaners to flush wastewater lines. Because amalgam waste may be mixed with body fluids or other potentially infectious material, use protective equipment such as utility gloves, masks, and protective eyewear when handling it. Check with city, county, or local waste authorities for an amalgam waste recycler and for any special requirements that may exist in the area for collecting, storing, and transporting amalgam waste. Store amalgam waste in a covered plastic container labeled "Amalgam for Recycling" or as directed by the recycler. Store different types of amalgam (e.g., contact and non-contact) in separate containers for recycling.
Amalgam capsules	Do not use bulk elemental mercury, also referred to as liquid or raw mercury. Use pre-capsulated alloys and stock a variety of capsule sizes. Recycle used disposable amalgam capsules. Do not put disposable amalgam capsules in biohazard containers, infectious waste containers (red bags), or regular garbage.
Non-contact amalgam	Salvage, store, and recycle non-contact amalgam. Do not put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage. Place unused non-contact amalgam in a silver or gray storage container or a storage container with a silver or gray label (keep containers sealed at all times).
Contact amalgam	Salvage amalgam pieces from restorations after removal and recycle the amalgam waste. Do not put contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage. Recycle teeth that contain amalgam restorations after confirming with the recycler that they will accept extracted teeth with amalgam restorations. Do not dispose of extracted teeth that contain amalgam restorations in biohazard containers, infectious waste containers (red bags), sharps containers, or regular garbage. Do appropriately disinfect extracted teeth that contain amalgam restorations (e.g., 10 minutes in a 1:10 bleach-to-water solution). Place unused contact amalgam in a silver or gray storage container or a storage container with silver or gray label (keep containers sealed at all times).

Table 6-1. ADA BMPs for Dental Amalgam

Focus	Best Management Practice
Chair-side traps	Use chair-side traps to retain amalgam and recycle the content. Do not rinse chair-side traps containing amalgam over drains or sinks. Disposable traps from dental units dedicated strictly to hygiene may be placed in with the regular garbage. Place disposable chair-side traps and the contents of reusable chair-side traps in a silver or gray storage container or a storage container with a silver or gray label (keep containers sealed at all times).
Amalgam separators	Select an amalgam separator that complies with ISO 11143. Follow the manufacturer's recommendations for maintenance and recycling procedures.
Other amalgam collection devices	Recycle contents retained by the vacuum pump filter, amalgam separator, or other amalgam collection device that may be used, if they contain amalgam. Do not rinse vacuum pump filters containing amalgam, amalgam separator canisters, or other amalgam collection devices that may be used over drains or sinks. Change the filter according to the manufacturer's recommended schedule. Place disposable vacuum pump filters and the contents of reusable vacuum pump filters in a silver or gray storage container or a storage container with silver or gray label (keep containers sealed at all times).
Bulk elemental mercury	Recycle bulk mercury. Check with licensed recycler to determine if they accept it. Do not pour bulk mercury waste in the garbage, into a red bag, or down the drain. Check with state regulatory agency and municipality to find out if a collection program is available.

Source: ADA, 2007.

6.2.2 ADA Nine Principles

In 2010, ADA adopted a resolution that endorses a mandatory national pretreatment standard for dental office wastewater if it is consistent with nine principles laid out in the resolution. The nine principles are (ADA, 2010):

1. Any regulation should require covered dental offices to comply with BMPs patterned on the those developed by ADA (see Table 6-1), including the installation of International Organization for Standardization (ISO) compliant amalgam separators or separators equally effective;

2. Any regulation should defer to existing state or local law or regulation requiring separators so that the regulation would not require replacement of existing separators compliant with existing applicable law;

3. Any regulation should exempt dental practices that do not place or remove amalgams, or only de minimis amounts of amalgams;

4. Any regulation should include an effective date or phase-in period of sufficient length to permit affected dentists a reasonable opportunity to comply;

5. Any regulation should provide for a reasonable opportunity for covered dentists to repair or replace defective separators without being deemed in violation of the regulation;

6. Any regulation should minimize the administrative burden on covered dental offices by (e.g.) primarily relying upon self certification (subject to verification or random inspection) and not requiring dental-office specific permits;

7. Any regulation should not include a local numerical limit set by the POTW;

8. Any regulation should not require wastewater monitoring at the dental office, although monitoring of the separators to assure proper operation may be required; and

9. Any regulation should provide that compliance with it shall satisfy the requirements of the Clean Water Act unless a more stringent local requirement is needed.

6.2.3 ADA Health First Amalgam Recovery Program

In 2013, ADA joined with HealthFirst to establish an amalgam recovery program. ADA chose HealthFirst as its endorsed amalgam recovery service provider. Through the HealthFirst Amalgam Recovery Program, ADA members are able to purchase an amalgam separator at a reduced cost. HealthFirst also offers waste handling services, including arranging the shipment, tracking, and documentation of waste to permitted waste handlers. In addition, other supplies such as chair-side traps, filters, and ADA-approved amalgam buckets can also be purchased through the program (ADA News, 2013; ADA Business Resources, 2014).

6.3 STATE DENTAL AMALGAM REQUIREMENTS

EPA identified 12 states as having mandatory program requirements for dental offices; 11 of which require amalgam separators:

- Connecticut;
- Louisiana;[18]
- Maine;
- Massachusetts;
- Michigan;
- New Hampshire;
- New Jersey;
- New Mexico;
- New York;
- Rhode Island;

[18] Louisiana state requirements under the Mercury Risk Reduction Act do not specifically require dental offices to install amalgam separators; dental offices must follow 1999 BMPs recommended by the ADA. ADA did not add amalgam separators to its list of BMPs until 2008.

- Vermont; and
- Washington.

At proposal of the draft dental category rule, EPA identified Oregon as a state with a mandatory dental amalgam control program. However, based on a follow up discussion with Oregon's Department of Environmental Quality, EPA found that the program is handled by the Oregon Dental Association and is voluntary (ERG, 2016).

States typically use the voluntary BMPs developed by ADA described above as the basis for their dental mercury discharge regulations. As a result, the state requirements share several common elements. Table 6-2 summarizes the elements of the various state regulations, including the types of requirements included and the methods used to demonstrate compliance with the regulations. Table 6-3 compares the state BMP requirements to the ADA BMPs.

Table 6-2. Summary of Elements of State Requirements

Element	Examples from State Requirements
Requirements	Install amalgam separators (CT, LA, MA, ME, MI, NH, NJ, NM, NY, RI, VT, WA). Follow state BMPs (CT, LA, MA, MI, NH, NJ, NY, RI, VT, WA). Do not flush waste amalgam down the drain (CT, LA, MA, MI, NH, NJ, NY, RI, VT). Use neutral (or non-oxidizing) line cleaners (CT, LA, MA, MI, NJ, NY, RI, VT)
Amalgam separator technology specifications	Meet ISO 11143 Standard (CT, MA, ME, MI, NH, NJ, NM, NY, RI, VT, WA). Operate at 95% efficiency (CT, MI, NH, NM, NY, VT). [a] Operate at 98% efficiency (MA, ME). [a] Operate at 99% efficiency (NY if new, RI).
Method for demonstrating compliance	Submit certification to state environmental agency or Control Authority (CT, LA, MA, ME, NH, NJ, NM, NY, WA). Maintain maintenance and servicing records (CT, MA, ME, NM, NY, RI, VT). Maintain amalgam recycling or disposal records (CT, LA, MA, ME, NM, RI, VT).

Sources: U.S. EPA, 2016a; ERG, 2016.

a – In several states, if an office had an amalgam separator in operation prior to implementation of the state law, then the state allowed the office to continue operating that separator at its current efficiency.

State dental mercury control programs specifically require amalgam separators that meet the ISO 11143 standard except for Louisiana. Louisiana does not specifically require the use of amalgam separators. Rather, the rule requires dental offices to meet the ADA guidelines effective June 2006. ADA did not add the use of amalgam separators to its BMPs until 2008.

The majority of state programs that do specify meeting the ISO 11143 standard do not explicitly state the standard year. Eight state programs have initiation or compliance dates prior to 2008 (Connecticut, Louisiana, Maine, Massachusetts, New Hampshire, New York, Vermont, and Washington), three in 2008 (Michigan, New Jersey, and Rhode Island), and one since 2008 (New Mexico).

The majority of state programs require the following BMPs, as described by ADA BMPs:

1. Do not flush amalgam waste down the drain or toilet, and do not rinse chair-side traps or vacuum pump filters containing amalgam over drains or sinks.[19]

2. Do not use bleach or chlorine-containing cleaners to flush wastewater lines.[20]

Table 6-3. Mandatory BMPs by State and Comparison to ADA BMPs [a,b]

Best Management Practice	ADA	CT	LA	MA	ME	MI	NH	NJ	NM	NY	RI	VT	WA
Initial Use													
Use only pre-capsulated alloys and/or stock a variety of capsule sizes.	X	X	X			X	X	X		X			
Do not use bulk mercury.	X		X			X		X		X			
Recycling/Disposal													
Manage amalgam waste through recycling as much as possible.	X	X	X	X			X	X		X	X		
Recycle used disposable amalgam capsules.	X		X			X	X	X		X	X	X	X
Do not flush amalgam waste down the drain or toilet.	X	X	X	X		X	X	X		X	X	X	X
Salvage, store and recycle non-contact amalgam (scrap, or waste, amalgam).	X	X	X	X		X	X	X		X	X	X	X
Salvage amalgam pieces from restorations after removal (contact amalgam) and recycle amalgam waste.	X	X	X	X		X	X	X		X	X	X	
Recycle teeth that contain amalgam restorations.	X		X	X		X	X			X		X	X
Do not put used disposable amalgam capsules in biohazard containers, infectious waste containers (red bags) or regular garbage.	X	X	X			X	X	X		X	X	X	X
Do not put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags) or regular garbage.	X	X	X	X		X	X	X		X	X	X	X
Do not put contact amalgam waste in biohazard containers, infectious waste containers (red bags) or regular garbage.	X	X	X	X		X	X	X		X	X	X	
Do not dispose of extracted teeth that contain amalgam restorations in biohazard containers, infectious waste containers (red bags), sharps containers or regular garbage.	X		X	X		X	X	X		X	X	X	

[19] EPA included a similar BMP in the final rule: waste amalgam (contact and noncontact), including but not limited to dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices must not be flushed to the sewage collection system.

[20] EPA included a similar BMP in the final rule: chair-side traps and vacuum lines that discharge to the sewage collection system must be cleaned with neutral cleaners that have a pH between 6 and 8.

Table 6-3. Mandatory BMPs by State and Comparison to ADA BMPs [a,b]

Best Management Practice	ADA	CT	LA	MA	ME	MI	NH	NJ	NM	NY	RI	VT	WA
Chair-Side Traps													
Use chair-side traps to retain amalgam and recycle the content.	X		X	X		X	X	X		X	X	X	X
Do not rinse chair-side traps containing amalgam over drains or sinks.	X	X	X	X			X	X		X	X	X	X
Where appropriate, disposable amalgam traps are preferable to reusable traps.		X					X			X	X		
Vacuum Pumps													
Recycle contents retained by the vacuum pump filter or other amalgam collection device, if they contain amalgam.	X	X	X	X		X	X			X	X	X	X
Do not rinse vacuum pump filters containing amalgam or other amalgam collection devices over drains or sinks.	X	X	X	X			X	X		X	X	X	X
Use line cleaners that minimize the dissolution of amalgam.	X		X	X						X	X	X	
Do not use bleach or chlorine-containing cleaners to flush wastewater lines.	X	X	X	X		X		X		X	X	X	
Amalgam Separators													
Install and use amalgam separators.	X	X	X	X	X	X	X	X	X	X	X	X	X
Other													
If using mercury, maintain a mercury spill kit on site and train all staff on mercury spill cleanup response procedures.		X		X			X				X	X	
Do not disinfect teeth or any item that contains amalgam using heat.				X		X	X			X			

Sources: ADA, 2007; CTDEP, 2006; Lamperti, 2007; Louisiana Legislature, 2006; MassDEP, 2007; Michigan, 2012; NHDES, 2002; NJR, 2007; NYDEC, 2007; RIDEM, 2007; VTDEC, 2006; and WADOE, 2005.

a – Neither Maine nor New Mexico included any BMPs as part of its requirement to install amalgam separators (Maine DEP, 2005; New Mexico, 2014).

b – Louisiana state requirements under the Mercury Risk Reduction Act do not specifically require dental offices to install amalgam separators; however, dental offices must follow BMPs recommended by the ADA. These BMPs include the installation of amalgam separators (Louisiana Legislature, 2006).

Three states, Maine, New Mexico, and Washington do not list the BMPs as a state requirement or only list them as guidance. New Hampshire requires the first BMP (no flushing), but does not require the second BMP (use of neutral cleaners).

All states administer their programs through state environmental agencies. Most require at least one-time reporting, however EPA did not find reporting requirements for three of the state programs (Michigan, Rhode Island, and Vermont).

In addition to states with mandatory programs, four states (Florida, Idaho, Minnesota, and Oregon) and the District of Columbia provide voluntary guidelines and BMPs to dental offices. Table 6-4 summarizes the BMPs for these states and district and compares them to ADA's BMPs.

Table 6-4. Voluntary BMPs by State and Comparison to ADA BMPs

Best Management Practice	ADA	DC	FL	ID	MN	OR
Initial Use						
Use only pre-capsulated alloys and/or stock a variety of capsule sizes.	X	X	X	X		X
Do not use bulk mercury.	X	X	X	X		X
Recycling/Disposal						
Manage amalgam waste through recycling as much as possible.	X	X	X	X	X	X
Recycle used disposable amalgam capsules.	X	X		X		
Do not flush amalgam waste down the drain or toilet.	X	X	X		X	X
Salvage, store, and recycle non-contact amalgam (scrap, or waste, amalgam).	X	X		X	X	X
Salvage amalgam pieces from restorations after removal (contact amalgam) and recycle amalgam waste.	X	X	X	X	X	X
Recycle teeth that contain amalgam restorations.	X		X	X		
Do not put used disposable amalgam capsules in biohazard containers, infectious waste containers (red bags), or regular garbage.	X	X	X		X	X
Do not put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage.	X	X	X		X	X
Do not put contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage.	X	X	X		X	X
Do not dispose of extracted teeth that contain amalgam restorations in biohazard containers, infectious waste containers (red bags), sharps containers, or regular garbage.	X		X		X	X
Chair-Side Traps						
Use chair-side traps to retain amalgam and recycle the content.	X	X	X	X	X	X
Do not rinse chair-side traps containing amalgam over drains or sinks.	X	X	X	X	X	X
Where appropriate, disposable amalgam traps are preferable to reusable traps.			X			X
Vacuum Pumps						
Recycle contents retained by the vacuum pump filter or other amalgam collection device, if they contain amalgam.	X	X	X		X	X
Do not rinse vacuum pump filters containing amalgam or other amalgam collection devices over drains or sinks.	X	X	X		X	X
Use line cleaners that minimize the dissolution of amalgam.	X				X	
Do not use bleach or chlorine-containing cleaners to flush wastewater lines.	X	X			X	

Table 6-4. Voluntary BMPs by State and Comparison to ADA BMPs

Best Management Practice	ADA	DC	FL	ID	MN	OR
Amalgam Separators						
Install and use amalgam separators.	X			X	X	X
Other						
If using mercury, maintain a mercury spill kit on site and train all staff on mercury spill cleanup response procedures.		X	X			
Do not disinfect teeth or any item that contains amalgam using heat.					X	X

Sources: ADA, 2007; District of Columbia Water and Sewer Authority, 2012; FLDEP, 2001; ISDA, 2008; MDA, 2003; Oregon State Legislature, 2007.

6.4 LOCAL DENTAL AMALGAM REQUIREMENTS

EPA identified and reviewed 18 mandatory dental amalgam control program requirements for the following localities that are not located in a state with a mandatory program:

- East Bay Municipal Utility District (EBMUD), Oakland, CA;
- Palo Alto, CA;
- Central Contra Costa Sanitary District, Martinez, CA;
- San Jose, CA;
- Castro Valley, CA;
- San Francisco, CA;
- City of Fort Collins, CO;
- Boulder, CO;
- Metropolitan Wastewater Reclamation District, Denver, CO;
- City of Loveland, CO;
- Northeast Ohio Regional Sewer District, Cleveland, OH;
- Eau Claire, WI;
- Madison, WI;
- Milwaukee, WI;
- Wausau, WI;
- Green Bay-De Pere, WI;
- Waukesha, WI; and
- Watertown, WI.

EPA also identified programs in Rhode Island (Narragansett Bay) and Washington (King County Wastewater Treatment Division); however, all dental offices in those localities are covered under the state program.

Sixteen of the 18 local programs specifically require amalgam separators that meet the ISO 11143 standard. The other two programs are Palo Alto, California, which only refers to the

ADA BMPs (and did not include amalgam separators at the time of the program initiation); and Central Contra Costa Sanitary District in Martinez, California, which requires an amalgam separator but does not specify meeting the ISO 11143 standard. The majority of local programs that do specify meeting the ISO 11143 standard do not explicitly state the standard year.

The majority of local programs require the following BMPs, as described by ADA BMPs:

1. Do not flush amalgam waste down the drain or toilet, and do not rinse chair-side traps or vacuum pump filters containing amalgam over drains or sinks.

2. Do not use bleach or chlorine-containing cleaners to flush wastewater lines.

The Central Contra Costa Sanitary District in Martinez, California does not list the BMPs as part of its program, and EPA did not find information on the program for Eau Claire, Wisconsin (identified in comments to the proposed rule). The Northeast Ohio Regional Sewer District, Cleveland, Ohio program does not list the second BMP to use non-oxidizing line cleaners. Three of the programs had no flush provisions but slightly more limited wording (San Jose, California; Fort Collins, Colorado; and Boulder, Colorado).

As part of its costing analysis (see Chapter 9), EPA determined the number of dental offices in localities and states with mandatory dental amalgam control programs. EPA assumed that the dental offices located in an area with a mandatory program have amalgam separators installed. Lists the number of dental offices by state and locality.

Table 6-5. Number of Dental Offices Located in States and Localities with Dental Amalgam Control Program

State	Dental Offices that May Place or Remove Amalgam [a]	Locality	Dental Offices in State or Local Program [b]
California	18,472	East Bay Municipal Utility District (EBMUD), Oakland	404
		Palo Alto	114
		Central Contra Costa Sanitary District, Martinez	214
		San Jose	744
		Castro Valley	unknown
		San Francisco	571
		TOTAL	**2,047**
Colorado	2,437	City of Fort Collins	61
		Boulder	90 [c]
		Metropolitan Wastewater Reclamation District, Denver	800 [c]
		City of Loveland	30
		TOTAL	**981**
Connecticut	1,554	Not applicable – state program	1,554
Louisiana	1,396	Not applicable – state program	1,396

Table 6-5. Number of Dental Offices Located in States and Localities with Dental Amalgam Control Program

State	Dental Offices that May Place or Remove Amalgam [a]	Locality	Dental Offices in State or Local Program [b]
Maine	418	Not applicable – state program	418
Massachusetts	2,790	Not applicable – state program	2,790
Michigan	3,739	Not applicable – state program	3,739
Minnesota	1,738	Voluntary program through Minnesota Dental Association	1,477[d]
New Hampshire	533	Not applicable – state program	533
New Jersey	4,184	Not applicable – state program	4,184
New Mexico	603	Not applicable – state program	603
New York	8,088	Not applicable – state program	8,088
Ohio	3,774	Northeast Ohio Regional Sewer District (NEORSD), Cleveland and Solon	104
Rhode Island	345	Not applicable – state program	345
Vermont	227	Not applicable – state program	227
Washington	3,106	Not applicable – state program	3,106
Wisconsin	1,850	Eau Claire	24
		Green Bay-De Pere	142
		Madison	110 [c]
		Milwaukee	360
		Watertown	8
		Waukesha	22
		Wausau	14
		TOTAL	**680**

a – The count of dental offices is based on the number of offices in the state as reported in the 2012 Economic Census and national percent of dental offices that are general practices and specialty practices that may place or remove amalgam (U.S. EPA, 2016b).

b – Estimated number of dental offices that may place or removal amalgam that discharge to the locality POTW or total in state for mandatory state programs (U.S. EPA, 2016c).

c – Number of dental offices based on comment submitted on the proposed pretreatment standards for the dental category. Boulder: EPA-HQ-OW-2014-0693-0445; Denver: EPA-HQ-OW-2014-0693-0500; Madison: EPA-HQ-OW-2014-0693-0428.

d – Voluntary program where 85 percent of dental offices committed to install amalgam separators (Walsh, 2007).

6.5 VOLUNTARY PROGRAMS

Some states and localities have initiated voluntary dental mercury reduction programs. The following two subchapters summarize voluntary local programs that provided information to EPA on the participation rates for their programs. All of the programs involve outreach to dentists to educate them on BMPs and use of amalgam separators. The level of interaction between the program partners and local dentists varies greatly from program to program. Follow-up activities to verify participation include surveys, visits to dental offices, and contacting amalgam separator vendors and waste haulers for lists of customers. In some cases, the available information did not give EPA enough details to determine how the programs verified the participation rates. Table 6-6 summarizes the voluntary programs and presents the participation rates for the programs. This table also contains some state voluntary program participation rates for comparison purposes.

6.5.1 Voluntary Programs with High Participation Rates

This subchapter describes case studies of three voluntary programs (Duluth, Minnesota; Wichita, Kansas; and Massachusetts) that achieved participation rates greater than 90 percent or exceeded their goals for participation rates. It includes both local and state programs.

The Duluth, Minnesota program attributed its success to the following:

- High level of cooperation from local dental societies;
- One-on-one interaction with dentists; and
- Providing financial incentives to dentists.

Wichita and Massachusetts each took a two-phase approach to their programs. Phase 1 encouraged early installation of amalgam separators. Both states' programs included specific goals and deadlines for participation. The second phase of the program implemented mandatory requirements for installation of amalgam separators at dental offices. Both states reported participation rates exceeding 50 percent for the voluntary phase. Based on the success of its voluntary program, Kansas decided not to implement mandatory requirements. Massachusetts decided to implement mandatory requirements under phase 2; however, the state rewarded the dental offices that voluntarily installed amalgam separators during phase 1 by allowing them to operate amalgam separators at a lower efficiency than the separators required under phase 2.

Duluth, Minnesota

In 1992, the Western Lake Superior Sanitary District ("WLSSD," i.e., Duluth) and the Northeast District Dental Society formed a public-private partnership that taught dentists how to recycle amalgam waste, made presentations at local dental society meetings, and prepared and distributed written materials. As an incentive, the WLSSD purchased and installed separators at 51 dental offices, but left the largest long-term cost (recycling the amalgam) to be paid by the dentists (Walsh, 2007). ADA attributed the success of the program to the leadership of the local dental society, peer-to-peer interaction with area dentists (including explaining the need to properly manage amalgam waste to prevent mercury from entering the environment and demonstrating the proper methods for doing so), financial incentives to install amalgam separators, and a discount waste disposal option through WLSSD's "Clean Shop" Program. As of 2007, all of the dental offices had installed amalgam separators.

Wichita, Kansas

In April 2000, the Wichita Department of Water and Sewer initiated a code of mercury management practices, which requires dental offices in Wichita to be equipped with devices to reduce the amount of amalgam discharged into POTWs. Phase 1 was an effort to encourage voluntary use of technologies beyond the chair-side trap and vacuum filter (e.g., an amalgam separator). Phase 2 of the program would have required mandatory separators if the voluntary effort were not successful. Phase 2 of the program was never implemented because originally 60 percent of the dental community complied voluntarily. According to ADA, as of 2007, 98 percent of the 200 dental offices in the city have complied with the program without a mandatory separator requirement (Walsh, 2007).

Massachusetts

In 2004, the Massachusetts Department of Environmental Protection (MassDEP) worked with the Massachusetts Dental Society to establish a voluntary program for dentists to install amalgam separators. The program used a two-phase approach:

- First, MassDEP implemented a voluntary program that encouraged dental offices to install and use amalgam separators. The program's goals called for 50 percent participation by January 2005, 90 percent by January 2006, and 100 percent by January 2007.

- Second, MassDEP implemented mandatory requirements, described in Chapter 6.3, for operating amalgam separators, recycling amalgam waste, and certifying compliance.

The voluntary portion of the program reported a 75 percent participation rate for the first year, exceeding MassDEP's goals. In April 2006, MassDEP promulgated regulations mandating that most dental offices install separators. Dentists who had complied with the voluntary program were rewarded with an exemption from the regulation (i.e., record keeping and reporting) until 2007 or 2010, depending on how early they had complied. In addition, dentists who installed separators under the voluntary program were permitted to continue operating their separators at 95 percent efficiency. The regulation required all newly installed amalgam separators to operate at 98 percent efficiency (MassDEP, 2007).

Table 6-6. Summary of Voluntary Programs for Reducing Dental Amalgam Releases to Wastewater

State (Jurisdiction)	Date	Description	Participation Rate	Verification of Participation
California (Palo Alto, San Francisco, and Central Contra Costa)	No information	Voluntary installation of amalgam separators and implementation of BMPs.	65%	Survey conducted by sanitation districts in 2000.
Kansas (City of Wichita)	April 2000	Developed a code of mercury management practices. Encouraged dentists to use technologies beyond chair-side trap and vacuum filter (e.g., amalgam separator). Planned to require mandatory installation of amalgam separators if participation in the voluntary program had been low, but found that a mandatory requirement was not necessary.	98% (out of 200 offices)	No information.
Massachusetts (MA Dental Society)	2004	Goals were to have 50% of dentists install amalgam separators by January 2005, 90% participation by 2006, and 100% participation by 2007. MA later implemented mandatory requirements for amalgam separators.	April 2005 — 75%	No information.
Minnesota (MN Dental Association)	2001	Voluntary installation of amalgam separators.	85% of dentists have committed to installing separators.	No information.
Minnesota (City of Duluth)	2001-2003	Sanitation district purchased and installed amalgam separators in dental offices. Dentists are responsible for cost of recycling. The sanitation district and local dental society also provided education on how to recycle amalgam waste, trained personnel at dental offices, prepared written materials, and made presentations at dental society meetings.	100%	Sanitation district paid for and oversaw the installation of all amalgam separators.
Minnesota (Minneapolis, St. Paul)	2003	Voluntary installation of amalgam separators. 700 clinics participated in program. The voluntary program was accompanied by a threat of eventual regulation and an industrial permit requirement.	99% of the clinics eligible for the program installed separators.	No information.

Table 6-6. Summary of Voluntary Programs for Reducing Dental Amalgam Releases to Wastewater

State (Jurisdiction)	Date	Description	Participation Rate	Verification of Participation
Missouri (Springfield)	2006	University of Missouri conducted a study to determine whether voluntary BMPs could significantly reduce mercury discharges from dental offices. Offered a half-day training course on BMPs. Also sent outreach materials via mail to local members of the dental society. Collected wastewater samples to determine mercury reductions.	254 members in the local dental society. 54 (21%) of local dentists attended the half-day training session on BMPs. 76 (30%) of dentists indicated that they had implemented BMPs as a result of outreach. Very few dentists installed amalgam separators.	UM sent a follow-up survey to the 254 members of the local dental society.
Oregon (City of Corvallis)	2003	Voluntary installation of amalgam separators and implementation of BMPs. Corvallis was awarded EPA's 2006 National First Place Clean Water Act Recognition Award for Pretreatment Program Excellence.	100%	No information.
Washington (WA Dental Association)	August 2003	Voluntary installation of amalgam separators and implementation of other BMPs.	80% and anticipates an additional 16%	No information.
Washington (Seattle and King County)	No information	Significant outreach to dental offices on proper management of scrap (waste) amalgam, proper use of chair-side traps and pump filters to manage waste, and amalgam separators. Participation rate was so low that King County decided to implement a mandatory program.	<50% managed scrap amalgam properly. 25% installed amalgam separators. 10% contracted with waste haulers.	King County: Made unannounced visits to 212 dental offices. Contacted separator vendors to obtain lists of dental office customers. Contacted waste haulers and mail-away firms to obtain lists of dental office customers.
Wisconsin (Madison)	1997	Encouraged use of amalgam separators through outreach to dentists. Chapter 6.5.1 describes the mandatory program implemented by the locality.	23 of 103 dentists in the area (22%).	Surveyed local dentists to determine how many clinics use and/or remove amalgam and how many had installed amalgam separators.

Sources: Larry Walker Associates, 2002; MassDEP, 2007; MU Extension, 2007; Walsh, 2007; KCWTD, 2007; MMSD, 2008.

6.5.2 Voluntary Programs with Low Participation Rates

Two voluntary programs had participation rates below 50 percent. Similar to the programs with high participation rates, these programs conducted extensive outreach to local dentists to educate dentists on BMPs and the use of amalgam separators. Despite this effort, participation in the programs remained low leading one of the two programs to implement mandatory requirements for BMPs and amalgam separators.

Seattle and King County

In 1995, the Seattle–King County Dental Society set up a standing committee to work with the King County government. These partners met several times a year and pursued a number of activities listed below (Cain and Krauel, 2004). The Society won a regional environmental achievement award for its efforts to educate its members concerning mercury in dental wastewater.

- Developing a poster and a handbook for dentists;
- Writing articles for a dental journal;
- Mailing information to all members;
- Co-sponsoring a free waste pick-up event; and
- Presenting a "Green Dentistry" session at two Pacific Northwest Dental Conferences.

Other efforts undertaken independently by King County included:

- Advertisements seeking to educate dentists;
- Outreach to dental supply houses;
- Outreach to vocational/technical programs for dental assistants;
- Cash rebates for purchase of amalgam separators (up to $500);
- Technical assistance visits to dental offices; and
- Promotion of participating dentists as "EnviroStars."

During the fall of 1999 and spring of 2000, King County evaluated its voluntary dental program by conducting random visits to 212 dental offices and collecting data on the disposal of scrap (waste) amalgam, amalgam from chair-side traps, and pump filter sludge. King County also contacted separator vendors to obtain lists of dental offices that had purchased and installed separators, and of waste haulers and mail-away firms to obtain lists of dental offices with waste management contracts.

King County's evaluation showed that the six-year voluntary program achieved the following results (Cain and Krauel, 2004):

- Less than half of dentists in the King County service area properly managed waste amalgam.

- Less than 25 percent of dentists properly managed chair-side trap and pump filter waste.
- Only 25 dental offices installed amalgam separators (2.5 percent of those estimated to place and/or remove amalgam).
- Approximately 10 percent of dental offices contracted with waste haulers and/or mail-away firms.
- Hundreds of pounds of mercury from dental amalgams were still being disposed of annually in garbage, "red bags," sewers, and "unknown" places.
- The costs for King County's voluntary program totaled over $250,000. During 1995–2001, the program spent an estimated $4,500 on advertisements, $24,000 on the production of a poster and handbook, $65,000 on equipment rebates, $63,500 on field visits, and $100,000 for staff time.

Due to the lack of success of this voluntary program, King County began a mandatory program as of July 2003. Table 6-6 describes the mandatory regulations (KCWTD, 2007).

Springfield, Missouri

The Springfield program included extensive outreach to local dentists and was very successful in getting dentists to follow voluntary BMPs. However, the program was unsuccessful in getting dentists to install amalgam separators. The program staff concluded that amalgam separators were not installed because they are not required.

In 2006, the University of Missouri (MU Extension) began a study to determine whether dental offices could significantly reduce their mercury discharges through voluntary BMPs. Springfield was selected for the pilot study based on interest and commitment of staff resources from the Springfield Public Works Department and the Greater Springfield Dental Society (GSDS) (MU Extension, 2007). The discussion of this study presented in this chapter focuses on participation rates for the voluntary program. Chapter 7 of this document discusses effectiveness of BMPs on reducing mercury concentrations at POTWs.

MU distributed a questionnaire to Springfield dentists in February 2006 to collect baseline data on amalgam use and management practices. The questionnaire was sent to 123 dentists and there were 48 responses (39 percent). MU then offered area dentists a half-day training course on BMPs for dental amalgam. Eighty dentists and dental office staff representing 54 local dental offices attended the training. Participants received a DVD, a wall poster with BMPs, a brochure of other available resources, and other written materials including:

- Dental mercury hygiene recommendations;
- ADA Guidelines on Amalgam Accumulations in Dental Office Plumbing;
- ADA Summary of Recent Study of Dental Amalgam in Wastewater;
- The Missouri Department of Natural Resources' determination of status and options for various types of dental amalgam waste; and

- A list of amalgam recyclers.

MU Extension also sent training materials by mail to dentists who did not attend the course.

One year later, MU Extension distributed a follow-up questionnaire to 254 members of the GSDS to measure any changes in management practices that resulted from MU's education efforts. The response rate was 30 percent (76 dental offices). The comparison of responses on reported dental amalgam management practices before and after intervention showed that the BMP training and education efforts may have succeeded in changing some practices:

- Dental amalgam use decreased 5 percent from the previous year.
- Improper disposal of capsules in regular waste decreased after the training and education, while the number of dentists reporting setting amalgam capsules aside for pickup by an amalgam recycler increased significantly.
- The collection and recycling of waste amalgam increased significantly after BMP training while the improper disposal decreased.
- The amount of amalgam waste disposed of as medical waste after the BMP training increased slightly. This finding may indicate a need for additional education for dental office staff and better labeling and instruction from medical waste management companies.
- Use of chair-side traps increased from the year before; the practice of disposing of trap contents with regular waste decreased.
- More of the dentists who used pump filters reported placing filter contents in a container with medical waste. Also reported was a slight increase in placing filter contents in a container for pickup by an amalgam recycler. Fewer dentists reported that they place filter contents in regular office waste.
- More dentists reported that they disinfected extracted teeth with amalgam restorations and set them aside for an amalgam recycler.
- More dentists reported using an amalgam recycler and that their recycler also picked up medical waste. However, the majority of dentists reported that they were unable to recycle amalgam waste because they could not locate a recycler in their area, locate a recycler to pick up small quantities of dental amalgam waste, find a method for shipping waste, or afford recycling amalgam.

According to the results of the survey, MU's efforts were successful in educating dentists on BMPs. However, the majority of the dentists in the Springfield area did not use amalgam separators prior to outreach and did not install amalgam separators after MU conducted its outreach. MU concluded that very few dentists use amalgam separators because they are not required in Missouri or Springfield (MU Extension, 2007).

6.5.3 Summary of Participation Rates in Voluntary Programs

Participation rates in voluntary programs are highly variable, ranging from as high as 100 percent of dentists in a community to as low as approximately 20 percent. Several programs that experienced low participation rates conducted extensive outreach and had frequent interaction with dentists. Therefore, the level of participation did not necessarily correspond to the level of outreach and education. In a study prepared for the Association of Metropolitan Sewerage Agencies (AMSA), the author noted that during the first year of implementation, regulatory programs have higher participation rates than voluntary programs. However, over time (5 to 10 years), participation rates for well-implemented voluntary programs are similar to participation rates for mandatory programs (Larry Walker Associates, 2002).

Voluntary programs that included the threat of a mandatory second phase had the highest participation percentages. Examples of the mandatory second phase requirements included more stringent requirements for reporting, or the requirement for higher amalgam separator efficiency standards. To avoid the more stringent mandatory requirements, dental offices usually opted to comply with the voluntary requirements. In addition, voluntary control programs that directly purchased amalgam separators for the dentists to install were very successful.

The level of interaction between the program partners and local dentists varies greatly from program to program. Follow-up activities to verify participation include conducting surveys, visiting dental offices, and contacting amalgam separator vendors and waste haulers for lists of customers.

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Chapter 7
Treatment Technologies and Best Management Practices (BMPs)

Dental offices employ various technologies and approaches for reducing or eliminating pollutant discharges. As described earlier, some dental offices do not install or remove amalgam. For those dental offices that do place or remove amalgam, as described in Chapter 5, chair-side traps and vacuum pump filters reduce the pollutants in dental amalgam discharges. Further reductions can be achieved by adding amalgam separators. To reduce the dissolved portion of metals, dental offices can incorporate polishing technologies. Dental offices can also install wastewater retention tanks to eliminate discharges to publicly owned treatment works (POTWs). Finally, as described in Chapter 6, best management practices (BMPs) are integral to reducing pollutants in dental discharges.

This chapter describes amalgam separators and polishing, including information on treatment efficiency, and wastewater retention tanks. It also discusses BMPs that EPA identified to reduce the discharge of dental amalgam resulting from activities not directly related to amalgam restoration or removal.

7.1 AMALGAM SEPARATORS

An amalgam separator is a device designed to remove solids (including amalgam) from dental office wastewater. Dental wastewater that goes into the chair-side cuspidors might not go through the amalgam separator, but dental practices can connect the chair-side drain to the vacuum system.[21] The amalgam separator is placed at a 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 office's vacuum to draw wastewater into the separator. However, the separation of solids from the wastewater and the flow of the wastewater out of the separator will depend on the design of the separator. A typical plumbing configuration for a dental office outfitted with an amalgam separator is shown earlier in this document, in Figure 5-1. Prior to wastewater entering the amalgam separator, some dental amalgam is removed by the chair-side traps and vacuum filter traps. Dentists maintain the traps by removing the solid particles collected by them into a bucket or other storage container, then recycling or properly disposing of the dental amalgam waste (ERG and SolmeteX, 2011a). The wastewater flow rate determines how often filters and traps need to be cleaned/replaced (Walsh, 2007).

7.1.1 Treatment Process, Design, and Operation

The configuration, size, and operation of the dental office all affect the choice of separator design. Amalgam separators can use sedimentation, filtration, centrifugation, ion exchange, or a combination of some or all of these methods to remove dental amalgam (ADA, 2007). Practically all amalgam separators currently on the market today use sedimentation processes (with or without filtration) to settle out the solids from the wastewater because of its

[21] Gravity-feed amalgam separators might also be installed at dental offices.

effectiveness and operational simplicity. The high specific gravity of amalgam causes it to settle readily from suspension in wastewater, which allows the dental office wastewater to be treated effectively by sedimentation techniques (Fan et al., 2002). 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 pulled through the separator. Sedimentation-based separators are the simplest types of separators to operate.

Filtration can enhance solids removal in sedimentation-based amalgam separators, or may function as the primary treatment process of the separator (Fan et al., 2002). EPA is aware of at least one type of separator that uses centrifugation, in which a centrifuge-based separator spins the water and forces the heavier amalgam particles to the sides of the separator, while the water discharges from the separator.

A few amalgam separators combine sedimentation (with or without filtration) with ion exchange in the same unit. Ion exchange technology removes dissolved mercury by using a chelating agent or proprietary resin. These separators often require special cleaning or additives to maintain their efficiency. A few dental offices operate a separate ion exchange (or polishing) system to remove dissolved mercury after the wastewater leaves the amalgam separator. See Chapter 7.2. None of the separators that EPA identified in the literature review added chemicals to enhance solids removal, although chemical and polymer additions have been effective in precipitating a portion of dissolved mercury out of dental wastewater under certain conditions (Fan et al., 2002).

There are two common designs for amalgam separators. The first is a two-chambered separator design that consists 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 top of the separator 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 unit. The wastewater leaves its solids in the filter, then continues through the vacuum system and eventually discharges from the dental office and then to the sewer. The second 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 and remains in the separator for some time, allowing the solids to settle. For either design, when the filtration cartridge or the separator itself reaches its capacity for retained solids, the cartridge must be replaced and/or the separator serviced by the recycling or waste vendor (ERG, 2010 and ERG, 2011b).

The performance of the amalgam separator depends directly on specific operational, maintenance, and inspection activities. 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 is vital that the unit be checked periodically, and serviced if necessary. Further, it is preferable for the dental office to visually identify when an amalgam separator is approaching capacity (such as indicators for 75 or 90 percent filled), as opposed to waiting until the device is at capacity and/or an alarm sounds indicating the device is full. Manufacturers will typically recommend the frequency of checks and service to ensure proper operation.

Solids collected by the amalgam separator may include dental amalgam, biological material from patients, and any other solid material sent down the vacuum line. Manufacturer instructions for servicing amalgam separators and for handling separator waste should be followed. Some amalgam separator manufacturers also offer waste management services. Services provided can include ensuring that waste collected by the separator is handled according to state and local requirements, and providing necessary compliance documentation for the office's recordkeeping requirements. If such services are not employed, the office should dispose of amalgam waste in accordance with state and local requirements.

7.1.2 Standards for Amalgam Separators

The vast majority of amalgam separators on the market today have been evaluated for their ability to meet the current American National Standards Institute's (ANSI) Standard for Amalgam Separators (ANSI/ADA Standard No. 108 for Amalgam Separators). ANSI is the coordinator of the U.S. voluntary consensus standards system. An International Organization for Standardization (ISO) document may be nationally adopted as an ANS as written or with modifications to its content that reflect technical deviations to the ISO standard that have been agreed upon through a consensus process. In other words, a consensus of U.S. experts, in an open and due process based environment, agreed that ISO 11143 with U.S. modifications is appropriate for adoption as an ANS. This ANSI standard incorporates the ISO Standard for Dental Amalgam Separators (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42288).

The current ISO standard for amalgam separators is ISO 11143. ISO established a standard for measuring amalgam separator efficiency by evaluating the retention of amalgam solids using specified test procedures in a laboratory setting. In order to meet the ISO standard, a separator must achieve 95 percent removal or greater of total solids. The solids sample must be prepared from dental amalgam as detailed in the standard, and summarized below. The ISO standard also includes certain design requirements and requirements for instructions for proper use and maintenance. In addition, the U.S. EPA has evaluated some amalgam separator devices under the Environmental Technologies Verification (ETV) program.

ISO Standard 11143. ISO 11143 calls for measuring amalgam separator efficiency by evaluating the retention of particles that contain dental amalgam. ISO Standard 11143 requires that an amalgam separator remove at least 95 percent by weight of amalgam particles (i.e., the mixture of mercury with other metals that constitute the amalgam filling) when subjected to a specific test method as detailed in the standard. The test for determining the efficiency must be carried out when the amalgam separator is under both empty and full conditions. The ISO test for removal efficiency uses 10.00 grams of amalgam particles that are composed of three portions of different sizes (ISO, 2008):

- 60 percent of the particles are 3.15 millimeters (mm) or smaller and larger than 0.5 mm.
- 10 percent of the particles are 0.5 mm or smaller and larger than 0.1 mm.
- 30 percent of the particles are 0.1 mm or smaller.

It also includes requirements that instructional material supplied by the manufacturer include directions for use, operation, and maintenance. The standard classifies amalgam separator systems by the method of separation: centrifugation, sedimentation, filtration, or combination of the first three methods.

It is important to note that compliance with this standard is based not on total mercury concentration in effluent wastewater, but on particle removal. To test the efficiency of an amalgam separator, a slurry of water and amalgam is poured into the amalgam separator and effluent water is collected. This effluent wastewater is filtered through a series of pre-weighted filters, the filters are dried and weighed, and the final weight of the filters is then compared against the original weight (Batchu et al., 2006a). ISO Standard 11143 describes the set-up of the testing apparatus, installation of the amalgam separator, step by step procedures to perform the efficiency testing, and how to calculate the efficiency of the amalgam separator.

The ISO Standard 11143 also requires that amalgam separators include a warning system to indicate when the collecting container should be emptied or replaced (before maximum fillable volume is reached). The standard also requires an alarm system to indicate when the collecting container has reached the maximum filling level specified by the manufacturer. The alarm signal must remain activated until the dentist empties or replaces the collecting container and/or filter. A final alarm system is also required to indicate a malfunction of the amalgam separator.

Other requirements of the ISO Standard 11143 include a removable filling container for the amalgam separator that the dentist can easily and safely remove without discharging any of the contents into the public sewage system, a maximum fillable volume of the collecting container (4 liters), and electrical safety requirements for installing an amalgam separator.

EPA/Environmental Technology Verification (ETV) Standard. The EPA/ETV program has developed a standard more rigorous than ISO 11143. The EPA/ETV standard, "Protocol for the Verification of Hg Amalgam Removal Technologies," uses a concentration-based criterion and measures efficiency as a function of mercury concentration as opposed to particulate removal (NSF International, 2001). EPA/ETV protocol recommends using Standard Methods 3500-Hg for sample collection, preservation, analysis, and storage. Standard Methods 3500-Hg is a cold vapor atomic absorption method for determining the concentration of mercury in potable water (APHA et al., 1998). The EPA/ETV standard protocol is not used nearly as widely as the ISO Standard, likely due to its higher cost and the longer time required for sample analysis. See http://www.epa.gov/etv/pubs/04_vp_mercury.pdf.

7.1.3 Treatment Efficiencies for Amalgam Separators

Dental offices commonly use amalgam separators in conjunction with chair-side traps and vacuum pump filters. Most chair-side traps can filter particles as small as 0.7 millimeter (mm) and vacuum filter traps can capture particles as small as 0.4 mm (Fan et al., 2002). The combined removal rate of a well operated chair-side trap and vacuum filter is approximately 78 percent of amalgam particles (Vandeven and McGinnis, 2005). When chair-side traps and vacuum pump filters are used upstream of amalgam separators, the combined treatment system can achieve removal rates exceeding 99 percent (Fan et al., 2002).

Studies have demonstrated that amalgam separators can achieve significant reductions in the amount of mercury discharged from dental wastewater.

- A 1998 Boston University study tested three commercially available amalgam separators that used different separation technologies, including gravity settling, settling/filtration, and mechanical centrifuge. The amalgam removal, and thus the particulate mercury removal, efficiencies for the three technologies ranged from 95 to 99.9 percent. However, the study also noted that an effluent mercury concentration of 0.2 parts per million could not be consistently met without chemical treatment (Boston University, 1998).

- A 2001 study found that amalgam separators were able to remove 91 to 99 percent of amalgam particles (i.e., the metals that constitute the amalgam filling), with an average removal efficiency of 95 percent (MCES, 2001).

- EPA Region 8 has reported that a properly installed amalgam separator will achieve removal efficiencies ranging from 95 to 99.99 percent of particulate mercury (U.S. EPA, 2005).

Table 7-1 provides a non-inclusive list of 26 commercially-available amalgam separators, including manufacturer name, the type of particulate separation technologies used, and the amalgam removal efficiency based on ISO testing in a laboratory setting.[22] As illustrated, all separators meet or exceed the ISO Standard of 95 percent (amalgam solids efficiency), 23 separators exceed 97 percent efficiency, and 19 separators meet or exceed 99 percent efficiency of amalgam particle removal. The separators described in Table 7-1 achieved a median efficiency of 99.3 percent.

Table 7-1. Efficiency and Technology of 26 Amalgam Separators

Model	Manufacturer	Treatment Technology	Percentage of Amalgam Removed (by weight) [a]	Data Sources
AD 1000	American Dental Accessories	Sedimentation, filtration, ion exchange	99.3%	2,7
Amalgam Boss	M.A.R.S. Bio-Med Processes	Sedimentation, filtration, ion exchange	95.0%	3
Amalgam Collector CE18	R & D Services	Sedimentation	99.6%	1,9

[22] Mention of product and vendor names does not constitute an endorsement by EPA.

Table 7-1. Efficiency and Technology of 26 Amalgam Separators

Model	Manufacturer	Treatment Technology	Percentage of Amalgam Removed (by weight) [a]	Data Sources
Amalgam Collector CE24	R & D Services	Sedimentation	>99.9%	1,10
Amalgam Collector CH12	R & D Services	Sedimentation	>99.9%	1,10
ARU-10	Hygenitek	Sedimentation, filtration, ion exchange	>99.9%	5,11
Asdex AS-10	Capsule Technologies	Filtration	99.0%	1,12
Asdex AS-20	Capsule Technologies	Filtration	99.0%	1,12
Asdex AS-20	American Dental Accessories	Sedimentation	95.0%	1,5
Asdex AS-9	American Dental Accessories	Filtration	99.0%	7
BU10	Dental Recycling North America	Sedimentation	>99.9%	1,8
BU30	Dental Recycling North America	Sedimentation	>99.9%	1,8
CATCH^{HG} 400[b]	Rebec Environmental	Sedimentation	99.3%	13
CATCH^{HG} 1000[b]	Rebec Environmental	Sedimentation	99.3%	13
Custom system (previously Catch 9000 series) [b]	Rebec Environmental	Sedimentation	99.3%	13
ECO II	Metasys, distributed by Pure Water Development	Sedimentation	97.5%	1,4,5,10
Hg5	SolmeteX	Sedimentation	99.0%	1,14
Hg5 HV	SolmeteX	Sedimentation, filtration	98.5%	1,14
Hg5 Mini	SolmeteX	Sedimentation, filtration	99.4%	1,14
Liberty Boss	M.A.R.S. Bio-Med Processes	Sedimentation, filtration, ion exchange	99.4%	1,6
Merc II	Bio-Sym Medical	Sedimentation, filtration, ion exchange	98.2%	5,9
MRU10	Dental Recycling North America	Sedimentation, filtration	>99.9%	2,8
MRU30	Dental Recycling North America	Sedimentation, filtration	>99.9%	8
MSS 1000	Maximum Separation Systems	Sedimentation, filtration	99.5%	2,5,9

Table 7-1. Efficiency and Technology of 26 Amalgam Separators

Model	Manufacturer	Treatment Technology	Percentage of Amalgam Removed (by weight) [a]	Data Sources
MSS 2000	Maximum Separation Systems	Sedimentation, filtration	98.9%	2,4,5
Rasch AD-1500	American Dental Accessories	Sedimentation	95.0%	1,5
Median			**99.3%**	

a – This efficiency is based on the percentage of mercury in the form of dental amalgam removed by weight, as instructed in ISO Standard 11143.

b – As part of the proposed rule analysis, EPA included two models for each series number (400, 1000, and 9000) from Rebec Solutions. Based on a review of the company website, only one model for each series is now offered (Rebec Environmental, 2016). To estimate the percent removal, EPA calculated the average of the two models in the series. The removal efficiencies for the models are documented in ERG and Rebec Solutions, 2011.

Sources: (1) U.S. Air Force, 2011; (2) MCES, 2009; (3) MMSD and University of Wisconsin-Extension, 2006; (4) Fan et al, 2002; (5) McManus and Fan, 2003; (6) MARS Bio Med Processes, 2012; (7) ERG and American Dental Accessories, 2011; (8) ERG and DRNA, 2011; (9) Batchu, et. al., 2006a; (10) Cain and Krauel, 2004; (11) Condrin, 2004; (12) Capsule Technologies, 2011; (13) ERG and Rebec Solutions, 2011; (14) ERG and SolmeteX, 2011b. Removal efficiencies documented in ERG, 2014. Calculation of median percent efficiency documented in U.S. EPA, 2016.

7.2 POLISHING

Mercury from dental amalgam in wastewater is present in both particulate and dissolved form. The vast majority (>99.6 percent) is particulate (Stone, 2004). The soluble mercury can be removed using oxidation and chelation under appropriate conditions. An additional process (sometimes referred to as polishing) uses ion exchange to promote removal of dissolved mercury from wastewater. In contrast to amalgam separators that contain an ion exchange component in the same unit where solids are collected (as discussed in the previous chapter), polishing via ion exchange refers to a separate treatment system that removes dissolved mercury from wastewater after the wastewater has gone through the separator.

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 is advantageous because it removes very small amalgam and ionic mercury particles. Sedimentation (with or without filtration) alone does not remove dissolved mercury. Ion exchange might be useful, for instance, in municipalities that have concentration limits on mercury (McManus and Fan, 2003). EPA is not aware of any state regulations that require ion exchange.

For ion exchange to be most effective in removing dissolved mercury, the incoming wastewater should first have the solids removed and then be oxidized (creating a charge on the amalgam particles) in order for the resin, or other capturing material, to capture the dissolved mercury. Therefore, ion exchange will not be effective without first being preceded by a solids collector and an oxidation process. Mercury (Hg) in water will speciate into many complexes including organic complexes, non-charged species, negatively charged and positively charged species. The variability of Hg ion charges makes ion exchange ineffective as a removal technology under these conditions. The addition of chlorine to the wastewater as an oxidant is used to manage the different species of mercury complexes into a single species ($HgCl_2$) for adherence to a chelating resin. This was successful in the removal of mercury in solution from the wastewater of several medical waste incinerators (EPA-HQ-OW-2014-0693-0329).

In a pilot ion exchange installation in Virginia for the U.S. Navy, it was found that high levels of calcium in the water materially affected the removal rates and contact times required to remove mercury to low part per billion results. This study was done using a sulfhydryl chemistry applied to a polymeric, high surface area resin. Contact times to precipitate mercury from dissolved mercury in laboratory conditions required only one minute of empty bed contact time. Similar contact times were used in other applications quite successfully other than the pilot run in Virginia. It was also found in another application for wastewater treatment by the U.S. Navy that an activated carbon column and sub-micron filtration following the chelating resin showed good soluble mercury removals. The project was stopped due to the cost of mercury chelating resin in excess of $800 per cubic foot (ft3) (EPA-HQ-OW-2014-0693-0329).

These data suggest a 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 to remove both suspended and dissolved mercury. Those dental offices needing to employ polishing would likely need to add a separate ion exchange unit to remove additional mercury from the waste stream after it leaves the amalgam separator.

As explained above, testing for compliance with the ISO standards is based on an evaluation of the removal of amalgam solids in a laboratory setting and does not differentiate between the suspended and dissolved forms. In order to understand more fully the reductions in dissolved mercury that can be achieved with the addition of ion exchange polishing, EPA reviewed available performance data from actual installations of ion exchange units and amalgam separators in dental offices. EPA found the use of polishing is limited to a handful of dental offices and found just one study of polishing systems. This study evaluated the additional efficacy provided by polishing at two dental offices that were responding to sanitation district concerns over their mercury discharges. The two dental offices in a sanitary district in Colorado installed polishing columns with a holding tank to allow chlorine oxidation after the amalgam separator but prior to the ion exchange columns. Preliminary EPA Region 8 audits showed the total additional mercury reductions achieved by the polishing step were typically on the order of 0.5 percent (Garcia, 2009). This is consistent with the studies indicated above that demonstrate that amalgam separators alone (without polishing) can remove 99.3 percent of total mercury on average, and further consistent with other data showing dissolved mercury comprises a very small percentage of the total amount of mercury in dental amalgam. It is unclear whether any solid mercury was converted to dissolved mercury in these two systems, and additional monitoring data are not yet available.

EPA found limited data on the costs of polishing systems (ERG, 2011a). The capital costs of the polishing system, as a stand-alone system, are approximately four times that of the amalgam separator (ERG, 2011a). EPA expects additional costs would occur for added chemical use, the resin, regenerating the resin, filter replacement, and other operational costs. EPA is aware of a number of operating installations of filtration, followed by chelating resin followed by activated carbon followed by 0.5 micron filtration, at several large dental schools in the United States. However, the cost of these operations has yet to be collected and reported. Further, EPA lacks data as to whether typical dental buildings have adequate space to install the holding tanks and chemical feed tanks needed to oxidize the wastewater before treatment, as well as space for the polishing column itself.

7.3 WASTEWATER RETENTION TANKS

Wastewater retention tanks are used at dental offices to collect and retain all amalgam process wastewater.[23] The wastewater remains in the wastewater retention tank until it is pumped out of the tank and transferred to a privately owned wastewater treatment facility (also referred to as centralized waste treatment facilities or CWT facilities). This technology eliminates the discharge of amalgam process wastewater and the associated pollutants from a dental office to a POTW. However, EPA identified only one vendor of this treatment technology. The vendor has indicated that the technology is not available in all locations due to proximity of a privately owned wastewater treatment facility licensed for such wastes, and due to the space needed for holding tanks (Anterior Quest, 2015).

7.4 BEST MANAGEMENT PRACTICES

In addition to technologies, EPA also identified best management practices currently used in the dental industry (and included in the ADA BMPs) to reduce dental amalgam discharges. In particular, EPA identified two BMPs to control dental amalgam discharges that would not be captured by an amalgam separator and/or polishing unit. Oxidizing line cleaners can solubilize bound mercury. If oxidizing cleaners are used to clean vacuum lines that lead to an amalgam separator, the line cleaners may solubilize any mercury that the separator has captured, resulting in increased mercury discharges (Cain and Krauel, 2004; Batchu et al., 2006b). One BMP ensures the efficiency of amalgam separators by prohibiting use of oxidizing line cleaners including but not limited to, bleach, chlorine, iodine and peroxide, that have a pH lower than 6 or greater than 8.[24]

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

7.5 REFERENCES

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[23] Dental offices using wastewater retention tanks must ensure that the wastewater retention tanks collect all amalgam process wastewater. Any uncollected amalgam process wastewater that is discharged to the POTW is subject to the final rule.

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

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Chapter 8
Regulatory Options

As described below, EPA identified one technology that is available (as that term in used in the CWA) to control dental amalgam discharges from the dental category: amalgam separators. EPA further identified two best management practices (BMPs) that would further reduce discharges of dental amalgam.

8.1 Pretreatment Standards For Existing Sources (PSES)

EPA decided to establish PSES based on proper operation and maintenance of one or more ISO 11143[25] compliant amalgam separators and two BMPs – a prohibition on the discharge of waste (or "scrap") amalgam to publicly owned treatment works (POTWs) and a prohibition of the use of line cleaners that are oxidizing or acidic and that have a pH higher than 8 or lower than 6. EPA finds that the technology basis is "available" as that term is used in the Clean Water Act (CWA) because it is readily available and feasible for all dental offices subject to this rule. Data in the record demonstrate that the technology basis is extremely effective in reducing pollutant discharges in dental wastewater to POTWs as the median efficacy of International Organization for Standardization (ISO) compliant amalgam separators on the market in the U.S. is 99.3 percent (U.S. EPA, 2016a). Moreover, the American Dental Association (ADA) recommends that dentists use the technology on which this rule is based (ISO compliant amalgam separators and BMPs). Further, EPA estimates that 40 percent of dental offices potentially subject to this rule currently use amalgam separators on a voluntary basis or are in states or localities with laws requiring the use of amalgam separators (U.S. EPA, 2016b). Many dentists have used amalgam separators and BMPs for at least a decade. For those dental offices that have not yet installed an amalgam separator, EPA estimates this is a low-cost technology with an approximate average annual cost of $800[26] per office. EPA's economic analysis shows that this rule is economically achievable (see Chapter 10). Finally, EPA also examined the incremental non-water-quality environmental impacts of the final pretreatment standards and found them to be acceptable. See Chapter 14.

EPA did not establish PSES based on technologies that remove dissolved mercury such as polishing. EPA is not aware of any state or local regulations that require ion exchange or that require removal of dissolved mercury. Commenters raised operational concerns with ion exchange citing a pilot study for the department of Navy. EPA also lacks adequate performance data to assess the efficacy of polishing for nationwide use. While even very small amounts of mercury have environmental effects, EPA lacks sufficient data to conclude that there is a significant difference in the performance between traditional amalgam separators and polishing. Moreover, current information suggests that polishing is not available for nationwide use because the typical dental office may not have adequate space to install the treatment train needed for effective polishing and because there are few polishing systems on the market today in comparison to traditional amalgam separators. Lastly, EPA estimates that the capital costs of

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

[26] This estimate is based on the average annualized cost for dental offices that do not currently have an amalgam separator (U.S. EPA, 2016c).

the polishing system, as a stand-alone system, are approximately four times that of the amalgam separator, even though the costs for chemical use, regenerating the resin, filter replacement, and other operational costs were not reported (ERG, 2011). These factors led EPA to find that polishing is not ‘‘available’’ as that term is used in the CWA.

EPA also did not establish PSES based on wastewater retention tanks. Capital costs for wastewater retention tanks are approximately twice that of the amalgam separator (Anterior Quest, 2015). EPA does not have information on the costs incurred by the dental office to send the collected wastewater off-site to a privately owned treatment facility (may also be referred to as a centralized waste treatment facility or CWT). Furthermore, wastewater retention tanks require space, and EPA determined that the typical dental office may not have adequate space to install the tanks. In addition, EPA is only aware of one vendor currently offering this technology and service combination (vendor transfers the collected wastewater to a privately owned treatment facility), and the vendor’s service area is limited to a few states. Therefore, EPA did not find this technology to be available to the industry as a whole.

8.2 Pretreatment Standards For New Sources (PSNS)

EPA decided to establish PSNS based on the same technologies identified above as PSES. As previously noted, under section 307(c) of the Clean Water Act (CWA), new sources of pollutants into POTWs must comply with standards that reflect the greatest degree of effluent reduction achievable through application of the best available demonstrated control technologies. Congress envisioned that new treatment systems could meet tighter controls than existing sources because of the opportunity to incorporate the most efficient processes and treatment systems into the facility design. The technologies used to control pollutants at existing offices, amalgam separators and BMPs, are fully available to new offices. In addition, data from EPA’s record show that the incremental cost of an amalgam separator compared to the cost of opening a new dental office is negligible; therefore, EPA determined that the final PSNS present no barrier to entry (see Chapter 10). Similarly, because EPA projects that the incremental non-water quality environmental impacts associated with controls for new sources would not exceed those for existing sources, EPA concludes the non-water quality environmental impacts are acceptable. Therefore, this final rule establishes PSNS that are the same as those for PSES.

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

8.3 References

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Chapter 9
Costs of Technologies

This chapter provides information on EPA's approach for estimating incremental compliance costs for dental offices to implement the final rule. The subsections below present an overview of EPA's cost methodology, including use of model dental offices and calculation of increment compliance costs for dental offices.

9.1 Methodology For Developing Model Dental Office Costs

EPA estimated incremental compliance costs for dental offices to comply with the final rule using data collected through EPA's *Health Services Industry Detailed Study* (August 2008) [EPA-821-R-08-014], a review of the literature, information supplied by vendors, and data submitted with comments on the proposed rule. EPA estimated costs for the following components: one-time costs (purchase and installation of technologies and completion of the One-Time Compliance Report), annual costs that occur on a regular ongoing basis (e.g., inspection, operation and maintenance (O&M), and purchase of amalgam retaining units (e.g., containers, cartridges, or filters)), and recordkeeping costs.

The cost estimates reflect the incremental costs attributed only to this final rule. For example, offices required by a state or local program to have an amalgam separator compliant with the 2008 ISO 11143 standard (or its equivalent) will not incur costs to retrofit a separator as a result of this rule. Others may certify to their Control Authority that they do not place or remove amalgam. Such offices may still have costs under this final rule such as those associated with the one-time reporting requirement (One-Time Compliance Report) to certify to their Control Authority that they do not place or remove amalgam. EPA's cost methodology assumes dental offices would use the required BMPs in combination with amalgam separators that meet the 2008 ISO 11143 standard (see Chapter 7.1.2). All final cost estimates are expressed in terms of 2016 dollars.

EPA develops national level incremental cost estimates for dental offices within the scope of the regulatory options. In general, facility specific data can be used to determine what changes, if any, a given facility would likely need to make to meet the requirements of a regulatory option. This approach requires substantial facility-specific technical information. In the case of the dental category, EPA would need such data for approximately 117,000 dental offices estimated to be subject to the final 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 affected facilities, then calculate costs for each model facility. EPA can then determine how many affected facilities each model facility represents, and apply the appropriate model costs, thereby modeling the full universe of affected facilities. This is the approach EPA used to project the incremental costs to affected dental offices to meet the requirements in the final rule.

9.1.1 Model Dental Offices

Based on a review of the literature and discussion with amalgam separator vendors, EPA determined that the dental office characteristic that drives many of the costs associated with this rule is the number of chairs in an office. EPA developed costs for seven model dental offices, where each model is based on the number of chairs in an office. The ranges for each model are as follows: 1 to 2 chairs, 3 chairs, 4 chairs, 5 chairs, 6 chairs, 7 to 14 chairs (average of 10 chairs), and 15 chairs.

EPA developed the 15 chair model dental office specifically to represent large, institutional offices. Large, institutional dental offices (i.e., military clinics or dental schools) have a larger number of chairs than the typical dental office. EPA has cost information for five amalgam separators that have a maximum design ranging from 17-22 chairs. EPA also has costs for a unit that can be custom sized for chair sizes of 16 or greater. EPA used the information for these six separators to estimate costs for large, institutional facilities (U.S. EPA, 2016a). This is labelled as 15 chairs in the table below, since it represents a model with more than 7-14 chairs (the penultimate model chair size). EPA's costs for institutional facilities are likely overstated as they do not reflect opportunities the largest offices may have to share costs, and they do not assume any economies of scale. 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 amalgam separator rather than each office having its own separator. In addition, it is possible that the largest offices have multiple plumbing lines, in particular multiple vacuum systems, allowing the installation of dental amalgam separators (or equivalent devices) only for those chairs used for placing or removing amalgam.

9.1.2 Incremental Compliance Costs for Model Dental Offices

EPA developed two sets of costs for each model: one for dental offices that do not use an amalgam separator and one for offices that do use an amalgam separator.

For dental offices that do not currently use an amalgam separator, EPA included the following incremental compliance costs for dental offices to meet the requirements of the final rule:

- One-time costs (purchase and install a separator, One-Time Compliance Report): capital costs to purchase an amalgam separator that meets the 2008 ISO 11143 standard and associated installation costs. EPA also included capital and installation costs to replace the separator at the end of the assumed service life (10 years) in its economic analysis. Costs include those associated with the One-Time Compliance Report.

- Annual costs: labor costs associated with visual inspections and operation and maintenance of the separator (separator maintenance, recycling preparation), replacement of the amalgam retaining unit, and recycling services.

- Periodic costs: labor costs associated with separator repair and recordkeeping of the repair and other recordkeeping (documentation of visual inspections, separator maintenance, and recycling). EPA also included the cost associated with submitting a transfer in ownership form.

The following subchapters provide further details on each of these incremental compliance costs.

9.1.2.1 One-time Costs for Dental Offices

For those dental offices without an amalgam separator, EPA's cost methodology assumes dental offices would use 2008 ISO 11143 amalgam separators to comply with the rule. Many amalgam separator models are plumbed into the vacuum systems. However, chair-side traps and vacuums are installed as standard industry practice with dental chairs, and therefore EPA did not include capital costs for chair-side traps and vacuum systems as part of the incremental compliance costs of this rule (ERG & SolmeteX, 2011).

As shown in Table 7-1 in Chapter 7, EPA collected information on a non-inclusive list of 26 commercially-available amalgam separators identified by manufacturers as meeting the 2008 ISO 11143 standard[27]. EPA also used information on the amalgam separators included in Table 7-1 to estimate costs related to amalgam separators including purchase cost. Table 9-1 provides a summary of these separators and their related costs (in 2016 dollars). As shown in Table 9-1, the costs of amalgam separators vary, generally relative to the size (number of chairs) of the dental office. EPA assumed each model facility needs a single amalgam separator, with the separator size depending on the number of chairs in an office and the amalgam separator model. In some cases, a vendor offers more than one amalgam separator model than is designed to provide service for a specified number of chairs. EPA has not identified where purchase and installation of multiple smaller amalgam separator units would cost less than a single unit; however, to the extent the purchase and installation of multiple amalgam separators would be less expensive for a particular dental office, the costs used here are overstated. Similarly, if two or more dental offices, such as neighboring offices in a medical complex, could share an amalgam separator (taking advantage of economy of scale), EPA's costs are overstated. Manufacturer suggested retail prices (MSRP) range from $228 for a single chair unit to $4,510 (2016 dollars) for a custom unit serving over 15 chairs.

EPA calculated the one-time purchase costs as follows. EPA only used the costs of the 26 amalgam separators that meet the 2008 ISO 11143 standard. The separator costs are shown in Table 9-1, including the vendor specification of the number of chairs for which the specified separator model could be used. EPA's cost model includes several model dental offices that differ by the number of chairs: 1 to 2 chairs; 3 to 5 chairs; 6 chairs; 7 to 14 chairs; and 15 chairs including large institutional offices. Next EPA calculated the average cost of those separators that are appropriately used for each chair size model dental office. For example, the cost for an amalgam separator for an office with three to five chairs is the average cost of each amalgam separator model in Table 9-1 that could be used in a three to five chair office setting. See the MS Excel® *Cost Breakdown by Chair Size* (U.S. EPA, 2016a) for the detailed calculations.

[27] There may be additional amalgam separators on the market that meet the 2008 ISO 11143 standard for which EPA does not have information.

Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2016)

Manufacturer & Model Name	Treatment Technology	Number of Chairs	ISO Compliance Notes (Reference)	Equipment Cost $2016, (Capital)		Replacement Parts Cost $2016 (Annual O&M)			Recycling Cost $2016 Annual (g)	References
				Min	Max	Parts	Min	Max		
R & D Services: Amalgam Collector - CH12	Sedimentation	1 chair	Transparent container to monitor sludge collection (USAF, 2011); Yes (R&D Services, 2016)	$645.00	$645.00	Canister or Recycling service only (reuse canister)	$0.00	$345.14	$57.52	USAF, 2011; R&D Services, 2016
Capsule Technologies: Asdex AS-10	Filtration	1 chair	Yes. Procedures from manufacturer: when filter is 90% full, suction begins to degrade (USAF, 2011).	$252.50	$252.50	Filter (every 6 to 8 months)	$160.93	$214.57	Not included	USAF, 2011
American Dental Accessories: Asdex AS-9	Filtration	1 chair	Yes (ADA, 2007; ERG American Dental Accessories, 2011)	$227.52	$227.52	Filter (every 6 mos)	$173.28	$173.28	Not included	ERG & American Dental Accessories, 2011
Solmetex: Hg5 Mini (a)	Filtration, Sedimentation	1 to 4	Visual check of container fill level (USAF, 2011); ISO Certificate available online (Solmetex, 2016)	$812.76	$812.76	Collection container (every 6 to 12 mos)	$324.02	$648.04	$0.00	USAF, 2011; Solmetex, 2016
Capsule Technologies: Asdex AS-20 (a)	Filtration	2 to 4	Yes. Procedures from manufacturer: when filter is 90% full, suction begins to degrade (USAF, 2011).	$359.78	$359.78	Filter (every 6 to 8 months)	$321.85	$431.31	Not included	USAF, 2011
American Dental Accessories: Asdex AS-20 American Dental (a)	Sedimentation	1 to 4	Yes (ERG & American Dental Accessories, 2011)	$325.05	$325.05	Filter (change every 9 mos)	$255.67	$255.67	Not included	ERG & American Dental Accessories, 2011
Pure Water Development: ECO II	Sedimentation	1 to 5	Yes according to website (Pure Water Development, 2016)	$606.86	$606.86	Canister	$223.24	$223.24	$138.71	USAF, 2011

Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2016)

Manufacturer & Model Name	Treatment Technology	Number of Chairs	ISO Compliance Notes (Reference)	Equipment Cost $2016, (Capital)		Replacement Parts Cost $2016 (Annual O&M)			Recycling Cost $2016 Annual (g)	References
				Min	Max	Parts	Min	Max		
Rebec Environmental: CATCH^{HG} 400 (b)	Sedimentation	1 to 5	Company website marketing a CATCH^{HG} 400 amalgam separator that meets 2008 ISO 11143 standard (Rebec Environmental, 2016).	$1,284.16	$1,479.23	Canister (2 for plus series)	$482.24	$698.97	$0.00	Rebec Environmental, 2016; USAF, 2011
M.A.R.S. Bio-Med Processes: Amalgam Boss (c,d)	Filtration, Ion Exchange, Sedimentation	4 to 10	Visual check of separator fill level (USAF, 2011); ADA, 2007 indicates an alarm	$1,082.60	$1,082.60	Separator Unit	$1,082.60	$1,082.60	$0.00	USAF, 2011
R & D Services: Amalgam Collector - CE18	Sedimentation	1 to 6	Transparent container to monitor sludge collection (USAF, 2011)	$895.00	$1,320.00	Canister or Recycling service only (reuse canister)	$0.00	$287.62	$153.01	R&D Services, 2016; USAF, 2011
Hygenitek: ARU-10	Filtration, Ion Exchange, Sedimentation	1 to 6	Yes (NH, 2015)	$982.70	$982.70	Filter canister (every 6 mos) and Settling Tank (every 6 to 12 mos)	$403.41	$496.02	$0.00	SF Environment, 2005; McManus & Fan, 2003
Bio-Sym Medical Association: Merc II	Filtration, Ion Exchange, Sedimentation	1 to 8	Yes (NH, 2015)	$2,032.76	$2,032.76	Cartridge	$777.00	$777.00	$0.00	McManus & Fan, 2003

Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2016)

Manufacturer & Model Name	Treatment Technology	Number of Chairs	ISO Compliance Notes (Reference)	Equipment Cost $2016, (Capital)		Replacement Parts Cost $2016 (Annual O&M)			Recycling Cost $2016 Annual (g)	References
				Min	Max	Parts	Min	Max		
DRNA: BU10	Sedimentation	1 to 8	Yes, see http://www.drna.com/ISO_Compliant.html and NH, 2015 [Note ADA, 2007 state no intervention warning]	$812.76	$812.76	Canister (recycled)	$541.84	$541.84	$0.00	ERG & DRNA, 2011
DRNA: MRU10	Filtration, Sedimentation	1 to 8	NH, 2015 lists as ISO compliant; No intervention warning (ADA, 2007)	$1,354.60	$1,354.60	Canister (recycled)	$1,295.00	$1,295.00	$0.00	ERG & DRNA, 2011
Solmetex: Hg5	Sedimentation	1 to 10	Visual check of container fill level (USAF, 2011); ISO Certificate available online (Solmetex, 2016)	$812.76	$812.76	Canister/container (every 6 - 12 mos)	$324.02	$648.04	$0.00	USAF, 2011; Solmetex, 2016
M.A.R.S. Bio-Med Processes: Amalgam Boss (c, d)	Filtration, Ion Exchange, Sedimentation	4 to 10	Visual check of separator fill level (USAF, 2011); ADA, 2007 indicates an alarm	$1,082.60	$1,082.60	Separator Unit	$1,082.60	$1,082.60	$0.00	USAF, 2011
Maximum Separation Systems: MSS 1000	Filtration, Sedimentation	1 to 11	Yes (NH, 2015)	$1,523.30	$1,523.30	Settling Tanks	$211.04	$211.04	$290.39	MMSD & Univ of WI, 2006; McManus & Fan, 2003
American Dental Accessories: AD-1000 (e)	Filtration, Ion Exchange, Sedimentation	7 to 12	Yes (ERG & American Dental Accessories, 2011)	$862.61	$862.61	Filter (18 mos per dentist)	$760.46	$1,522.07	Not included	MCES, 2009; ERG and American Dental Accessories, 2011

Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2016)

Manufacturer & Model Name	Treatment Technology	Number of Chairs	ISO Compliance Notes (Reference)	Equipment Cost $2016, (Capital)		Replacement Parts Cost $2016 (Annual O&M)			Recycling Cost $2016 Annual (g)	References
				Min	Max	Parts	Min	Max		
American Dental Accessories: Rasch AD-1500 (e)	Sedimentation	7 to 12	Yes (ERG & American Dental Accessories, 2011)	$731.43	$731.43	Filter (18 mos)	$679.47	$1,357.85	$0.00	ERG and American Dental Accessories, 2011
R & D Services: Amalgam Collector - CE24	Sedimentation	1 to 12	Transparent container to monitor sludge collection (USAF, 2011).	$1,315.00	$1,740.00	Canister or Recycling service only (reuse canister)	$0.00	$345.14	$230.09	USAF, 2011; R&D Services, 2016
Rebec Solutions: CATCH[HG] 1000 (b)	Filtration, Sedimentation	6 to 15	Company website marketing a CATCH[HG] 1000 amalgam separator that meets 2008 ISO 11143 standard (Rebec Environmental, 2016).	$2,161.95	$2,177.12	Canister (2 for plus series)	$482.24	$698.97	$0.00	Rebec Environmental, 2016; USAF, 2011
Maximum Separation Systems: MSS 2000	Filtration, Sedimentation	12 to 22	Yes (NH, 2015)	$2,189.73	$2,189.73	Settling Tanks (2)	$518.00	$518.00	$580.79	McManus & Fan, 2003
M.A.R.S. Bio-Med Processes: Liberty Boss (f)	Filtration, Ion Exchange, Sedimentation	11 to 17	Visual check of separator fill level (USAF, 2011). ADA, 2007 indicates an alarm	$1,678.62	$1,678.62	Separator Unit	$1,678.62	$1,678.62	$0.00	USAF, 2011
DRNA: MRU30	Filtration, Sedimentation	1 to 20	NH, 2015 lists as ISO compliant; No intervention warning (ADA, 2007)	$1,945.21	$1,945.21	Canister	$1,511.74	$1,511.74	$0.00	ERG & DRNA, 2011

Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2016)

Manufacturer & Model Name	Treatment Technology	Number of Chairs	ISO Compliance Notes (Reference)	Equipment Cost $2016, (Capital)		Replacement Parts Cost $2016 (Annual O&M)			Recycling Cost $2016 Annual (g)	References
				Min	Max	Parts	Min	Max		
Solmetex: Hg5 High Volume	Filtration, Sedimentation	10 to 20	Visual check of container fill level (USAF, 2011); ISO Certificate available online (Solmetex, 2016)	$2,709.21	$2,709.21	Container (2), change every 6 to 12 mos	$650.21	$1,300.42	$0.00	USAF, 2011; Solmetex, 2016
Rebec Solutions: Catch 9000 (Custom systems) (b)	Sedimentation	16 to custom	Company website marketing custom systems that meet 2008 ISO 11143 standard (Rebec Environmental, 2016).	$4,509.85	$4,509.85	Container (3), change every year	$969.90	$969.90	$0.00	Rebec Environmental, 2016; USAF, 2011 ; MCES, 2009
DRNA: BU30	Sedimentation	7 to 20	USAF, 2011 says "yes"; no note about alarms; ADA, 2007 says no intervention warning	$1,511.74	$1,511.74	Canister, annual replacement	$812.76	$812.76	$0.00	USAF, 2011; ERG and DRNA, 2011

Source: U.S. EPA, 2016a.

a – Amalgam separator model can be used for either dental offices that have 1 to 2 chairs or dental offices that have 3 to 5 chairs. EPA used the costs associated with this particular model separator in its calculation of average costs for both model dental office size categories.

b – For proposed rule costing analysis, EPA included two Catch 400 series models; two Catch 1000 series models; and two Catch 9000 custom system models. Only one is now available as shown on website (Rebec Environmental, 2016), for final rule costing analysis, EPA used one separator of appropriate size.

c – Amalgam separator model can be used for dental offices that have 6 chairs or dental offices that have 7 to 14 chairs. EPA used the costs associated with this particular model separator in its calculation of average costs for both model dental office size categories.

d – Manufacturer recommends replacing unit every two years for 1 chair; every 1.5 years for 2 to 3 chairs; and every year for 4 - 10 chairs (USAF, 2011). EPA did not include this separator model in its calculation of average costs for the 1 to 2 chair or 3 to 5 chair model dental office size categories. To estimate compliance costs for the 6 chair model, EPA assumed the dental office would replace the unit at a minimum of once per year.

e – Manufacturer recommends replacing filter every 18 months for one dentist (MCES, 2009). To estimate annual cost for filter replacements, EPA assumed a dental office with 7 to 12 chairs would have 2 to 4 dentists. This assumption is based on the Safety Net Dental Clinic Manual which recommends 3 operatories (dental chairs) per dentist (National Maternal & Child Oral Health Resource Center, 2011).

f – Manufacturer recommends new unit every year for offices with 11 to 17 chairs (USAF, 2011).

g – Average recycling costs for all units is $82 per year ($2016).

For initial separator installation, EPA used a similar cost methodology. EPA obtained installation costs from multiple sources (Behm, 2008; ERG, 2010; King County, 2005; McManus & Fan, 2003; SF Environment, 2005; MMSD & University of Wisconsin - Extension, 2006; U.S. EPA, 2003). EPA then calculated the average installation cost for each model dental office based on the number of chairs represented by the model office: 1 to 2 chairs; 3 to 6 chairs; 7 to 14 chairs; and 15 chairs including large institutional offices. Available cost data do not differentiate between 3 to 5 chair offices and 6 chair offices, therefore the initial installation costs are the same for both sets of offices. EPA completed these calculations in the MS Excel® file, *Amalgam Sep Installation Costs* (U.S. EPA, 2016b). Separator purchase and installation costs were converted to 2016 dollars using RS Means Historic Cost Indexes. Table 9-2 presents the amalgam separator purchase costs (one-time capital costs) and installation costs that EPA calculated for each model dental office without an amalgam separator already in place.

Table 9-2. Summary of One-time Incremental Compliance Costs ($2016) to Model Dental Offices to Initially Purchase and Install Amalgam Separators

Cost Element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5	6	7 to 14	15
Separator Purchase	$437	$697	$1,058	$1,291	$2,424
Initial Separator Installation	$235	$276	$276	$358	$942
TOTAL	**$672**	**$973**	**$1,334**	**$1,649**	**$3,366**

Source: U.S. EPA, 2016c.

Some existing dental offices have already installed amalgam separators, either voluntarily or to comply with state or local requirements; see Chapter 6 of this document for more details. Under the final rule, such dental offices may continue to operate their existing amalgam separators for the remaining useful lifetime of the separator (or ten years, whichever comes first). Therefore, EPA did not include the initial costs for offices with amalgam separators currently in place to purchase and install another amalgam separator. The dental discharger must still comply with the other final rule requirements including the specified BMPs, operation and maintenance, reporting, and recordkeeping requirements. The compliance costs for these requirements is described in the Chapters 9.1.2.2 and 9.1.2.3.

In assessing the long term costs of rule compliance, available data indicate amalgam separators have a typical service life of at least 10 years, at which time the amalgam separators would need to be replaced (Vandeven and McGinnis, 2005). Consequently, for purposes of the economic analysis, in order to calculate annualized costs EPA assumes a 10-year life span of the separator. For offices with amalgam separators currently in place, the cost methodology also includes costs to install a new separator 10 years after the effective date of the rule as described above. Therefore, for the purposes of estimating compliance costs, EPA assumed all offices would incur the cost of installing a new amalgam separator no later than 10 years after the effective date of this rule. The separator cost was calculated using the purchase information in Table 9-2 as described above.

To assess the installation costs of the replacement separator at all dental offices, EPA assumes the major plumbing modifications needed by the office for initial amalgam separator installation would have already been completed. However, separator models may change and/or the plumbing needs may be slightly different. Therefore, EPA projected the installation costs for subsequent amalgam separators would be one-half of the cost of the original installation cost shown in Table 9-2. To the extent dental offices either close (discontinue operating) or certify they no longer remove or place amalgam, these costs are likely overstated.

One-Time Compliance Report

To calculate costs for dental offices to comply with the One-Time Compliance Report requirements in the final rule, EPA calculated a burden estimate as shown in Table 9-3. The rule requires submission of this report once per dental office; see § 441.50(a).

Table 9-3. Burden Estimate for One-time Compliance Report

Task	Time (minutes)
Read Instructions	3
Dental Practice and Address	1
Part I: Facility Information	2
Part II: Amalgam Handling	45
Obtain Signature	10
Submit to Control Authority	15
Total	76

EPA used the same reporting burden estimate for dentists that do not place any amalgam, and that only remove amalgam in limited emergency or unplanned, unanticipated circumstances. Although the actual time for these dental offices to complete the report is most likely less than dental offices that place or remove amalgam, EPA used the same value as a higher and therefore conservative cost estimate. These are the only costs such dental offices are expected to incur.

EPA assumed that a dental assistant, at a labor rate of $17.75 per hour (Bureau of Labor Statistics, 2015), would complete the reporting form. EPA also included the cost of postage ($0.49) for submitting the report. See Table 9-4 for the reporting costs for each model dental office. As shown, EPA estimated the one-time reporting cost to be $23. EPA included costs for all dental offices subject to the rule associated with a One-Time Compliance Report.

Table 9-4. Summary of One-Time Compliance Report Costs ($2016) to Model Dental Offices

Cost Element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5	6	7 to 14	15+
One-Time Compliance Report	$23	$23	$23	$23	$23

Source: U.S. EPA, 2016c.

9.1.2.2 Annual Costs for Dental Offices

Dental Offices without Amalgam Separators

Annual costs include replacement of the amalgam retaining unit (e.g., canister, cartridge, or filter); amalgam separator inspection costs; separator maintenance/cleaning costs, amalgam recycling preparation; and annual amalgam recycling costs. Each of these costs are detailed below.

- *Replacement of the amalgam-retaining unit*: For purposes of the cost model, replacement costs were calculated as the average of the amalgam separators appropriate for each group of model dental offices (i.e., based on the number of chairs in the office). The replacement cost of each type and size of amalgam separator is in Table 9-1, and the model dental office is described in Chapter 9.1.1. The average cost for each model dental office is in Table 9-6.

- *Recycling Service*: The rule requires that the amalgam retaining unit must be replaced in accordance with the manufacturer's schedule, or whenever the collection of retained solids reaches 95 percent of the manufacturer's stated design capacity, or annually, whichever comes first. See § 441.30 (a)(1)(vi). EPA included costs for dental offices to recycle the collected amalgam. As shown in Table 9-1, recycling cost vary from $0 (some vendors include recycling costs as part of the original purchase cost and/or replacement part cost) to $580 per recycling event. Where manufacturer recommendations for exchanging the canister or other amalgam retaining unit are not annual, the costs were pro-rated to an annual basis. See "Supporting Data for the Costing Analysis" (U.S. EPA, 2016d) and Chapter 16 for more details. For purposes of estimating national costs of this requirement, the average cost of annual recycling as reported for each separator is $82 (in 2016 dollars).

EPA included the following as annual O&M costs: inspection (assume monthly), separator maintenance (assume biweekly), and amalgam recycling preparation, as explained below:

- *Inspection*: The final rule requires the separator to be inspected in accordance with the manufacturer's operation manual; EPA assumed a monthly inspection for purposes of costing. Costs include a dental assistant ($17.75/hour) to perform a five-minute visual inspection monthly. This cost is included for all of the model dental offices.

- *Maintenance*: The final rule requires the separator to be maintained. This annual cost reflects costs to the dental office for maintenance activities that are beyond the cost of visual inspections and the replacement of the amalgam retaining unit. This cost also reflects the wide range of vendor cost data, and also includes contingency for unforeseen costs. For example, the amalgam retaining unit may need service or replacement more frequently than the manufacturer's minimum recommended change frequency, and other maintenance activities may include additional visual checks of the system such as checking the fill line when the unit does not have an audible alarm. For costing purposes, EPA assumed such maintenance would be performed by a dental assistant every two weeks and that each maintenance session would take 15 minutes (on average).

- *Recycling preparation*: As described above, EPA included annual costs for recycling the solids collectors and/or filters/cartridges by pro-rating each separator's recommended recycle frequency to a 12 month periodicity. Recycle preparation includes costs for a dental assistant ($17.75/hour) to spend 15 minutes to prepare the materials for shipping and recycling. Based on the typical recycling frequency of separators in Table 9-1, EPA assumes recycling occurs an average of two times per year. Therefore, the annual cost of recycle preparation is $9.

- *Vacuum system operation and maintenance cost off-set*: EPA included a negative incremental cost (cost off-set) associated with less frequent replacement and servicing of the existing vacuum system filter and impeller blade following installation of an amalgam separator. Over time, solid particulates (or abrasives) in the water passing through the wet vacuum system can cause the system to fail. Approximately 80 percent of dental offices use wet vacuum systems. As an alternative to replacing the wet vacuum system, dentists have maintenance performed on the vacuum (e.g., cleaning, repair, motor replacement). EPA included the cost offset for the decreased labor needed to maintain the vacuum system as a result of amalgam separator installation. Table 9-5 presents a comparison of the maintenance labor costs at a dental office with no amalgam separator in place and a dental office with an amalgam separator in place. Over a ten-year period, EPA expects the model dental office to have an annualized costs savings of approximately $75 per year (U.S. EPA, 2016d).

Table 9-5. Vacuum System Labor Cost Offset for Model Dental Offices Purchasing and Installing Amalgam Separators

Year	Maintenance Activity (Labor Rate: $150 per hour)	No Amalgam Separator	With an Amalgam Separator
0	Vacuum System Maintenance: 4 hours at labor rate of $150 per hour	$600	$600
3	For systems without amalgam separator, maintenance during year 3	$600	$0
5	For systems with amalgam separator, minor maintenance visit (1.5-hour visit)	$0	$225
6	For systems without amalgam separator, maintenance during year 6	$600	$0
9	For systems without amalgam separator, maintenance during year 9	$600	$0
10	Vacuum System Maintenance: 4 hours at labor rate of $150 per hour	$0	$600
10-year Total Maintenance Cost		$2,400	$1,425
10-year Cost Offset			$975
Annualized Cost Offset			$98
Annualized Cost Offset for Model Dental Office (accounts for 80% of dental offices using wet vacuum system)			**$78 (~$75 per year)**

Source: U.S. EPA, 2016d.

EPA does not project incremental compliance costs associated with the two BMPs required at § 441.30(b) because costs for non-oxidizing, pH neutral line cleaners are roughly equivalent to other line cleaners, and dental offices will not incur additional costs by changing the location for flushing waste amalgam.

Table 9-6 presents the annual costs for each of the components identified in this chapter. EPA converted replacement parts and recycling service costs to 2016 dollars using RS Means Historical Indexes. Costs are presented for each group of chair sizes that corresponds to one of EPA's model dental offices.

Table 9-6. Summary of Annual Costs ($2016) to Model Dental Offices Purchasing and Installing Amalgam Separators

Cost Element	Number of chairs in the model dental office				
	1 or 2	3, 4, or 5	6	7 to 14	15
Replacement Parts[a]	$275	$386	$559	$732	$1,078
Cost Offset for Vacuum System Maintenance	-$75	-$75	-$75	-$75	-$75
Visual Inspection (assumed Monthly)	$18	$18	$18	$18	$18
Separator Maintenance (assumed Biweekly)	$115	$115	$115	$115	$115
Recycling Preparation	$9	$9	$9	$9	$9
Recycling Service[a]	$82	$82	$82	$82	$82
TOTAL[b]	**$424**	**$535**	**$708**	**$881**	**$1,227**

Source: U.S. EPA, 2016c.

a – Replacement parts and recycling service costs converted to 2016 dollars using RS Means Historical Indexes.

b – Total for each model office size may not equal summation of individual costs presented due to rounding.

Dental Offices with Amalgam Separators

For dental offices that already have an amalgam separator, EPA included incremental costs for the same components described above for dental offices without amalgam separators: replacement of the amalgam retaining unit (e.g., canister, cartridge, or filter) if not already completed at least once per year; amalgam separator inspection costs; separator maintenance/cleaning costs; amalgam recycling preparation; and annual amalgam recycling costs. Offices that already have amalgam separators in place are already incurring the majority of these costs irrespective of this final rule. As such, for those components EPA calculated the incremental costs as a portion (percentage) of the annual costs incurred by dental offices without separator technology in place. More specifically, the incremental annual costs for those components for offices with amalgam separators are assumed to cost 50 percent of what the costs of these components are to an office that does not already have an amalgam separator. This is likely an overestimate of costs because state and local programs have largely reported successful implementation of requirements to install amalgam separators; see Chapter 6. Table 9-7 presents the annual incremental compliance costs that EPA calculated for the final rule for dental offices with an amalgam separator in place. Note that for inspection, EPA included the same costs for offices with and without separators because most state and local dental amalgam programs do not have such requirements, and EPA did not identify any data supporting a different approach.

EPA did not include the vacuum system operation and maintenance cost off-set because dental offices with amalgam separators already benefit from reduced vacuum repair as a result of the separator installation.

Table 9-7. Summary of Annual Costs ($2016) to Model Dental Offices with an Amalgam Separator in Place

Cost Element	Fraction of Cost Compared to Offices without Amalgam Separators	Number of chairs in the model dental office				
		1 or 2	3, 4, or 5	6	7 to 14	15
Replacement Parts[a]	50%	$138	$193	$280	$366	$539
Visual Inspection (assumed Monthly)	100%	$18	$18	$18	$18	$18
Separator Maintenance (assumed Biweekly)	50%	$58	$58	$58	$58	$58
Recycling Preparation	50%	$4.44	$4.44	$4.44	$4.44	$4.44
Recycling Service[a]	50%	$41	$41	$41	$41	$41
TOTAL[b]		**$258**	**$314**	**$400**	**$487**	**$660**

Source: U.S. EPA, 2016c.
a – Replacement parts and recycling service costs converted to 2016 dollars using RS Means Historical Indexes.
b – Total for each model office size may not equal summation of individual costs presented due to rounding.

9.1.2.3 Recordkeeping Costs

The final rule includes recordkeeping requirements that all dental offices, or an agent or representative of the dental office, will need to maintain: inspections, amalgam retaining unit replacement, amalgam recycling/disposal, separator maintenance, and records of repair and separator service. Costs associated with these recordkeeping requirements are detailed in this subchapter. EPA calculated recordkeeping costs using the following parameters:

- *Inspection*: EPA included costs for a dental assistant ($17.75/hour) to complete the documentation for required inspections, estimating it would take five minutes per month per inspection.

- *Maintenance*: EPA included costs for a dental assistant ($17.75/hour) to complete the documentation for maintenance, estimating it would take five minutes each occurrence. EPA assumed maintenance would occur every two weeks.

- *Recycling service*: EPA included costs for a dental assistant ($17.75/hour) to complete the documentation for recycling service, estimating it would take five minutes each occurrence. EPA assumed recycling services would occur annually.

EPA also estimated periodic reporting costs.

- *Transfers Ownership:* If a dental discharger transfers ownership of the facility, the new owner must submit a new One-Time Compliance Report to the Control Authority no later than 90 days after the transfer; see § 441.50(a)(4). These costs are assumed to incur at 10 percent of the dental offices when there is a transfer in ownership of the dental office. Since the form is the same, EPA used the same cost used for the initial One-Time Compliance Report ($23) described above in Chapter 9.1.2.1.

- *Separator repair:* As part of the final rule, dental offices must have amalgam separators repaired in the event they discover the unit is malfunctioning. For purposes of the cost analysis, EPA assumed the dental office will either be under a warranty program or will have a contract in place with the separator manufacturer to repair any malfunctioning amalgam separators. EPA included costs to the dental office for a dental assistant ($17.75/hour) to spend a total of 30 minutes to contact a repair person, oversee their work at the office, and document the repair (recordkeeping). Because of this recordkeeping component, EPA included the costs under periodic costs. Not all offices will need to have repairs occur each year. Vendors indicated that separators are primarily constructed of heavy duty plastic and have no moving parts, therefore repairs are infrequent. Based on vendor observations that separators rarely malfunction, EPA conservatively estimates one percent of offices would incur this cost annually ($17.75/hour × 0.5 hours × 1 percent).

Table 9-8 presents the annual recordkeeping costs that EPA calculated for dental offices to comply with the final rule. These costs apply to both dental offices without amalgam separators in place and dental offices with amalgam separators.

Table 9-8. Summary of Annual Recordkeeping Costs ($2016) to Model Dental Offices

Cost Element	Number of chairs in the model dental office				
	1 or 2	3,4, or 5	6	7 to 14	15
Recordkeeping: Visual Inspection	$18	$18	$18	$18	$18
Recordkeeping: Separator Maintenance	$38	$38	$38	$38	$38
Recordkeeping: Recycling	$2.96	$2.96	$2.96	$2.96	$2.96
Periodic Recordkeeping Costs					
One-Time Compliance Report (transfer of ownership)	$2.30	$2.30	$2.30	$2.30	$2.30
Separator Repair	$0.09	$0.09	$0.09	$0.09	$0.09
TOTAL[a]	**$62**	**$62**	**$62**	**$62**	**$62**

Source: U.S. EPA, 2016c.

a – Total for each model office size may not equal summation of individual costs presented due to rounding.

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Chapter 10
Economic Impacts for the Dental Industry

This chapter describes EPA's economic impact assessment of the dental category rule, and is organized as follows:

- Chapter 10.1 reviews the structure of the regulated sector in terms of number of dental offices potentially subject to the dental category rule and the distribution of these offices by revenue.

- Chapter 10.2 presents the compliance costs that EPA expects will be incurred by dental offices under the rule, and combines the estimates of numbers of offices subject to the rule by relevant operating characteristics to estimate total nationwide compliance costs for the rule.

- Chapter 10.3 summarizes the methods and results of several tests of the economic impacts of the rule.

- Chapter 10.4 assesses the social cost of the dental category rule, including costs to dental offices[28] and the costs to permitting authorities for administering rule requirements.

- Chapter 10.5 determines the potential for significant economic impact on small dental office entities as a result of the rule.

- Chapter 10.6 provides references for this chapter.

10.1 Overview Of Dental Offices Potentially Subject To Final Regulation

In this chapter, EPA reviews its estimate of the number of dental offices that might be subject to the rule, including:

- A review of information from the Economic Census and other sources on the number of offices in the dental sector.

- Adjustments to these counts to reflect baseline levels of (1) number of dental offices using mercury-containing materials (dental amalgam); (2) the number of dental offices that currently use treatment technology; and (3) as a result, the costs likely to be incurred by dental offices in complying with the rule.

[28] As explained in Chapter 2, dental offices include but are not limited to large institutions such as dental schools and clinics; permanent or temporary offices, home offices, and facilities; and including dental offices owned and operated by federal, state, or local governments including military bases.

10.1.1 Number of Dental Offices Potentially Subject to the Final Regulation

To support the assessment of total costs and economic impact of the final dental category rule, EPA relied on data from the 2012 Economic Census describing the number of firms and establishments in the dental office sector (NAICS 621210), and their annual receipts/revenue (U.S. Census Bureau, 2012a). EPA used the 2012 Census data for this analysis because these data are the most recent comprehensive public data on the dental office sector. Data on the number of dental office firms and establishments by revenue size are used to assess the number of regulated entities that may incur costs, the costs that these entities may incur (based on their scale of business operations and associated need for compliance technology), and thus the rule's total cost. These data are also used to assess the potential impact of a regulation in terms of the level of costs that may be incurred by individual firms/establishments and whether these costs would be unduly burdensome in relation to their ongoing revenue.

EPA determined that the operating characteristics of the individual dental offices — in particular, the number of dental chairs in the office — would be a key determinant of the technology response and associated compliance costs that would be incurred by dental offices in complying with the final dental category rule. Therefore, EPA estimated compliance costs for each dental office size. In addition, in reviewing 2012 Economic Census data for the dental office sector (U.S. Census Bureau, 2012b), EPA observed that almost all firms are single-establishment/single-office firms. The total of 133,221 establishments/offices is owned by 125,275 firms — thus no more than 10,557 offices, or fewer than 8 percent of offices, can be owned by multi-office firms. And only at the highest revenue ranges do firms frequently own and operate more than one office. Thus, as a practical matter, there is little difference between the number of dental offices and the number of dental firms. For this reason, EPA performed the impact analysis at the level of the office instead of the level of the firm.

Starting with the 2012 Economic Census counts of dental offices (U.S. Census Bureau, 2012a), EPA applied a number of adjustments to estimate the number of dental offices, in aggregate and by revenue range, that could be subject to the final Dental Amalgam Rule.

- As shown in Table 10-1, the Economic Census listed 133,221 dental offices in total. In addition, office counts are spread over 11 revenue ranges, ranging from the lowest range, $0–$10,000, to the highest range, $10,000,000 and up, based on 2012 dollars. EPA performed its cost and economic impact analysis based on 2016 dollar values. Because the Economic Census revenue ranges are defined in 2012 dollars, EPA adjusted these dollar values defining the revenue ranges to 2016 dollars using the GDP Deflator, a sector-/commodity-neutral basis for adjusting dollar values for general inflation over time. Table 10-1 lists the revenue range values in 2012 and 2016 dollars in the left set of columns of the table. This adjustment assumes that dental service prices matched the general rate of inflation over the 2012–2016 period, and that the industry remained constant in all other regards: total quantity of services provided and total number and distribution of offices by revenue range.

- Of the 133,221 total offices, the Economic Census reported 122,926 offices as being in business for the full 2012 year and 10,295 offices as being in business for only part of the year. The numbers of dental offices listed in the 11 revenue ranges represent the 122,926 offices that were in business for the full year. Because the revenue range of offices is important in estimating the compliance requirements that an individual office would face, and also for assessing small entity impacts, EPA assigned the remaining 10,295 offices (those in business for only part of the year) across the revenue ranges of offices that were in business for the full year, in the same proportion as the full year offices. EPA assigned these partial-year offices to the small business revenue ranges (the first nine ranges) to prevent potentially understating the number of small businesses that could incur costs as a result of the final dental category rule. The tenth revenue range includes the Small Business Administration revenue cutoff ($7.5 million), and EPA assigned none of the partial-year offices to this range.[29] The right-most column in Table 10-1 reports the numbers of offices by revenue range after this adjustment.

Table 10-1. Dental Office Establishments by Revenue Range (NAICS 621210, Offices of Dentists)

Revenue Ranges ($2012)		Revenue Ranges ($2016)		Number Establishments	Adjusted Number Establishments[a]
Low	High	Low	High		
0	$10,000	**$0**	$10,491	58	63
$10,000	$24,999	$10,492	$26,228	456	494
$25,000	$49,999	$26,229	$52,458	1,139	1,235
$50,000	$99,999	$52,459	$104,917	2,983	3,234
$100,000	$249,999	$104,918	$262,293	14,217	15,413
$250,000	$499,999	$262,294	$524,587	28,736	31,153
$500,000	$999,999	$524,588	$1,049,175	42,337	45,899
$1,000,000	$2,499,999	$1,049,176	$2,622,939	28,495	30,892
$2,500,000	$4,999,999	$2,622,940	$5,245,879	3,958	4,291
$5,000,000[b]	$9,999,999	$5,245,880	$10,491,759	474	474
$10,000,000	Or more	$10,491,760	Or more	73	73
Establishments operated for the entire year				122,926	133,221
Establishments not operated for the entire year				10,295	-
Total Establishments				**133,221**	**133,221**

Sources: U.S. Census Bureau, 2012a, U.S. EPA, 2016a

a – With establishments not operating for the entire year assigned to first nine revenue ranges.

b – Highlighting in the $5 million to $10 million revenue range indicates that this range contains the SBA small business size standard for offices of dentists.

In addition to the dental offices that are reported in the Economic Census, EPA estimates that dental services potentially within the scope of this regulation are performed at an additional 415 large institutional dental offices, including 65 dental schools and 350 military clinics (EPA-HQ-OW-2014-0693-0329). Adding these large offices to the 133,221 dental offices from the Economic Census brings the total of dental offices that are potentially subject to the rule to 133,636.

[29] See discussion in Chapter 10.5 for information on the assessment of small entity impacts.

10.1.2 Adjustments to Account for Baseline Status

EPA accounted for additional factors that will influence the extent to which dental office sector would incur costs under the dental category rule.

- First, EPA recognized that certain specialty dental practices do not place or remove dental amalgam (see Chapter 4.2) and thus did not include them in the scope of the final rule. These specialty practices are: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, and prosthodontics. Based on information from the American Dental Association (ADA), EPA estimated that 21 percent of total dental offices are specialty service practices (ADA, 2016). EPA assumed that, within specialty practices, only endodontists, pediatric dentists, and endodontists place or remove amalgam (Vandeven and McGinnis, 2005), or approximately 39.4 percent of specialty practices (based on data from ADA, 2016). As a result , EPA estimated that approximately 13 percent[30] of non-military dental offices are specialists that are not subject to the rule. Because the rule will not apply to them, EPA assigned no compliance-related costs to these 16,916 offices, and these offices are not included in the impacts analysis. This leaves 116,720 offices that are subject to the final rule.

- Second, based on information from U.S. EPA, 2016b, EPA assumes that all 350 military clinics already have amalgam separators in place.

- Third, EPA divided the non-military offices subject to the rule into two groups: (1) offices that have already installed amalgam separators and (2) offices without amalgam separators. Offices with amalgam separators already in place will incur lower costs relative to offices without treatment technology in place. EPA reviewed state and local requirements and estimated that 41 percent of offices have amalgam separators in place already (U.S. EPA, 2016c). EPA used this percentage to categorize all non-military offices as either "technology in place" or "no technology-in-place" offices. Using this approach, EPA categorized 47,942 offices as having technology-in-place, and the remaining 68,428 as no technology-in-place.

- Fourth, among the remaining offices subject to the rule that have not already installed amalgam separators, EPA estimated that approximately 20 percent do not place or remove dental amalgam (Pimpare, 2012) and thus would incur no treatment technology-related costs due to the dental category rule. These 13,686 offices would need to certify to their permitting authority that they do not process amalgam, for which the offices would incur a one-time only reporting cost.

Table 10-2 lists the numbers of dental offices by revenue range (from Table 10-1), and including large offices, with these further breakouts. EPA carried these estimated numbers of

[30] 21 percent (share of non-military offices that are specialty) times 61 percent (share of specialty offices do not place amalgam).

dental offices by baseline amalgam use and compliance status forward to the cost and economic impact analysis.

Table 10-2. Establishments Assigned to Regulation Analysis Category

Revenue Range (2016$)[a]		Number Establishments					
				Offices Subject to the Rule			
						No Tech in Place	
Low	**High**	**All Offices[b]**	**Specialty Offices Not Subject to Rule[c]**	**Military Clinics[d]**	**Tech-in-Place[e]**	**Using Amalgam**	**Not Using Amalgam[f]**
$0	$10,491	63	8	0	23	26	6
$10,492	$26,228	494	63	0	178	203	51
$26,229	$52,458	1,235	157	0	444	507	127
$52,459	$104,917	3,234	410	0	1,163	1,328	332
$104,918	$262,293	15,413	1,956	0	5,544	6,330	1,583
$262,294	$524,587	31,153	3,954	0	11,206	12,795	3,199
$524,588	$1,049,175	45,899	5,825	0	16,509	18,851	4,713
$1,049,176	$2,622,939	30,892	3,921	0	11,112	12,688	3,172
$2,622,940	$5,245,879	4,291	545	0	1,543	1,762	441
$5,245,880	$10,491,759	474	60	0	170	195	49
$10,491,760	$100,000,000	73	9	0	26	30	7
Dental schools/military clinics		415	8	350	23	27	7
Total		**133,636**	**16,916**	**350**	**47,492**	**54,742**	**13,686**

Source: U.S. EPA, 2016a

a – See Table 10-1.

b – See Table 10-1 for number of offices by revenue range.

c – Based on 21 percent of non-military offices being specialty and 61 percent of specialty offices not placing or removing any amalgam (ADA, 2016), or 12.69% of all non-military offices.

d – Number of military clinics based on EPA-HQ-OW-2014-0693-0329.

e – Based on a review of state and local separator programs and voluntary installation in locations without existing requirements (U.S. EPA, 2016c).

f – Based on assumption that 20% of dentists without existing separators in place do not place or remove amalgam (Pimpare, 2012).

10.2 Summary Of The Final Regulation And Compliance Costs

EPA developed national cost estimates for dental offices to purchase and install amalgam separators, maintain the separators (combination of annual part/supply costs and labor costs), recycle the dental amalgam waste, and comply with inspection and reporting requirements. EPA prepared the costs to the industry of implementing the rule, taking into account any dental amalgam control practices that are currently mandated by state and local pretreatment programs. EPA assumed there would be no increased costs to dental offices to implement the two best management practices (BMPs) in the rule.

10.2.1 Summary of Compliance Costs

Using the methodology described in Chapter 9, EPA developed compliance costs for model offices with and without amalgam separators. As described in Chapter 9, EPA assumed that offices with treatment-in-place would incur no cost for purchasing and installing compliance technology at the time of initial regulatory compliance. However, EPA estimated additional permit-related costs and some recurring incremental costs (i.e., annual and one-time costs) for such offices.

EPA developed compliance costs based on the number of dental chairs in an office, as discussed in Chapter 9.1. The number of operatory chairs is the key driver of cost because the treatment capacity, and thus cost, of amalgam separators is based on the number of chairs serviced by the separator. Accordingly, EPA estimated costs for these cost categories based on the numbers of chairs in an office, organized within number-of-chair ranges, as follows:

- 1 to 2 chairs;
- 3 chairs;
- 4 chairs;
- 5 chairs;
- 6 chairs; and
- 7 to 14 chairs.

EPA also estimated costs for dental schools and military clinics. For purposes of costs, EPA assumed that average dental schools and military clinics have 15 chairs.

Table 10-3 and Table 10-4 list estimated compliance costs for no-technology-in-place offices and technology-in-place offices, respectively, in 2016 dollars, by cost category and by size (i.e., number of chairs).

Table 10-3. Dental Office Compliance Costs by Number of Chairs, Offices with No Technology in Place (2016$)

Cost Element	Operating Size: Number of Chairs						
	1–2	3	4	5	6	7-14	15
Technology Installation and Other Startup Costs							
Equipment purchase	$437	$697	$697	$697	$1,058	$1,291	$2,424
Installation	$235	$276	$276	$276	$276	$358	$942
One-Time Compliance Report	$23	$23	$23	$23	$23	$23	$23
Annual Costs							
Replacement parts	$275	$386	$386	$386	$559	$732	$1,078
Separator maintenance	$115	$115	$115	$115	$115	$115	$115
Maintenance-related recordkeeping	$38	$38	$38	$38	$38	$38	$38
Recycling preparation	$9	$9	$9	$9	$9	$9	$9
Recycling service	$82	$82	$82	$82	$82	$82	$82
Recycling-related recordkeeping	$3	$3	$3	$3	$3	$3	$3
Visual Inspection	$18	$18	$18	$18	$18	$18	$18
Inspection-related recordkeeping	$18	$18	$18	$18	$18	$18	$18
Vacuum filter/impeller blade cost savings	-$75	-$75	-$75	-$75	-$75	-$75	-$75

Table 10-3. Dental Office Compliance Costs by Number of Chairs, Offices with No Technology in Place (2016$)

Cost Element	Operating Size: Number of Chairs						
	1–2	3	4	5	6	7-14	15
Periodic Costs[a]							
Change form (10% of offices)	$23	$23	$23	$23	$23	$23	$23
Repair-related recordkeeping (1% of offices)	$9	$9	$9	$9	$9	$9	$9

Source: U.S. EPA, 2016a; U.S. EPA, 2016c

a – EPA multiplies these periodic costs by the percentage when calculating annual costs (i.e., change form is $23*.10 = $2.3 and repair-related recordkeeping is $9*.01=$0.09, as shown in Chapter 9)

Table 10-4. Dental Office Compliance Costs by Number of Chairs, Offices with Technology in Place (2016$)

Cost Element	Operating Size: Number of Chairs						
	1–2	3	4	5	6	7-14	15
Technology Installation and Other Startup Costs							
Equipment purchase	$0	$0	$0	$0	$0	$0	$0
Installation	$0	$0	$0	$0	$0	$0	$0
One-Time Compliance Report	$23	$23	$23	$23	$23	$23	$23
Annual Costs							
Replacement parts	$138	$193	$193	$193	$280	$366	$539
Separator maintenance	$58	$58	$58	$58	$58	$58	$58
Maintenance-related recordkeeping	$38	$38	$38	$38	$38	$38	$38
Recycling preparation	$4	$4	$4	$4	$4	$4	$4
Recycling service	$41	$41	$41	$41	$41	$41	$41
Recycling-related recordkeeping	$3	$3	$3	$3	$3	$3	$3
Visual Inspection	$18	$18	$18	$18	$18	$18	$18
Inspection-related recordkeeping	$18	$18	$18	$18	$18	$18	$18
Vacuum filter/impeller blade cost savings	$0	$0	$0	$0	$0	$0	$0
Periodic Costs[a]							
Change form (10% of offices)	$23	$23	$23	$23	$23	$23	$23
Repair-related recordkeeping (1% of offices)	$9	$9	$9	$9	$9	$9	$9

Source: U.S. EPA, 2016a, U.S. EPA, 2016c

a – EPA multiplies these periodic costs by the percentage when calculating annual costs (i.e., change form is $23*.10 = $2.3 and repair-related recordkeeping is $9*.01=$0.09, as shown in Chapter 9)

In assessing the costs of compliance, EPA estimated that amalgam separator equipment would have a service life of 10 years, after which time the compliance equipment would need to be replaced. For the estimation of reinstallation costs, EPA assumed that offices, regardless of original technology-in-place status, would incur the full cost of purchasing compliance equipment at the time of technology reinstallation. However, because various modifications needed for equipment installation would have been completed during initial installation, EPA estimated, for reinstallation, that compliance equipment would be able to be installed at one-half the cost of the original installation. Further, EPA assumed that, after re-installation, dental offices would incur ongoing expenses in the same way as described in the preceding paragraphs and shown in Table 10-3 and Table 10-4.

To summarize, EPA accounted for the initial installation and re-installation requirement by building up costs, as described, for two separate analysis periods:

1. **Years 1–10.**[31] In this period, dental offices that place or remove amalgam and have no-technology-in-place are assumed to install compliance equipment, if needed, and incur other startup costs at the beginning of year 1. Recurring costs are then incurred, as described above, in years 1–10.

2. **Years 11–20.** In this period, all dental offices that place or remove amalgam are assumed to incur the cost of reinstalling compliance equipment at the beginning of year 11. Recurring costs are then incurred, as described, in years 11–20.

For the assessment of compliance costs to dental offices, EPA accumulated these costs on a present value basis at year 1 at a discount rate of 7 percent, which is intended to represent the opportunity cost of capital to society, on a pre-tax, constant dollar basis.[32] The resulting present value is then annualized over the full 20-year analysis period at the 7 percent interest rate. EPA used the resulting total annualized compliance costs in assessing the total estimated cost and impact of the rule to dental offices, as described in subsequent chapters. Table 10-3 and Table 10-5 report specific elements of compliance costs and summarize the tabulation of costs to develop estimates of the total annualized compliance cost to dental offices.

For no-technology-in-place and technology-in-place offices, Table 10-5 and Table 10-6, respectively, summarize the tallying of these costs according to the initial installation and reinstallation specifications, and present value and annualized cost calculations. For each installation event, the table reports the total initial outlay and annually recurring costs, as incurred, and then summarizes the tabulation of these costs on a present value basis. Initial technology installation costs are directly tabulated at the beginning of year 1 (the year of initial compliance), while reinstallation costs are first tabulated on a present value basis at the beginning of year 11, and then further discounted to the beginning of year 1. Both present values are then summed and annualized over 20 years at a 7 percent discount rate.

[31] Where year 1 would be the first year in which an office complies with the rule.

[32] For the assessment of the rule's social costs, EPA used an additional discount rate of 3 percent and applied a different discounting treatment (see Chapter 10.4).

Table 10-5. Summary of Annualized Compliance Costs[a] for Dental Office with No Technology in Place (2016$)

Cost Element	Operating Size: Number of Chairs						
	1–2	**3**	**4**	**5**	**6**	**7-14**	**15**
Initial Installation Analysis							
Total initial outlay	$695	$996	$996	$996	$1,357	$1,672	$3,389
Total annual (recurring) costs	$486	$597	$597	$597	$770	$943	$1,289
Present value total annual (recurring)	$3,410	$4,190	$4,190	$4,190	$5,405	$6,620	$9,050
Total present value, at year 1	$4,105	$5,186	$5,186	$5,186	$6,762	$8,292	$12,439
Reinstallation Analysis — Equipment Reinstalled at Beginning of Year 11							
Total initial outlay (0.5 installation charge)	$555	$835	$835	$835	$1,196	$1,470	$2,895
Total annual (recurring) costs	$486	$597	$597	$597	$770	$943	$1,289
Present value total annual (recurring)	$3,410	$4,190	$4,190	$4,190	$5,405	$6,620	$9,050
Total present value, at year 11	$3,965	$5,025	$5,025	$5,025	$6,601	$8,090	$11,945
Total present value, at year 1	$2,016	$2,554	$2,554	$2,554	$3,356	$4,113	$6,072
Combining Initial Installation and Re-Installation							
Sum, present values at year 1	$6,121	$7,740	$7,740	$7,740	$10,118	$12,405	$18,512
Total Annualized Cost	**$578**	**$731**	**$731**	**$731**	**$955**	**$1,171**	**$1,747**

Source: U.S. EPA, 2016a

a – Present values and annualized costs calculated using a 7 percent discount rate. All costs are on a pre-tax basis and as of the time of compliance by complying entities.

Table 10-6. Summary of Annualized Compliance Costs[a] for Dental Office with Technology in Place (2016$)

Cost Element	Operating Size: Number of Chairs						
	1–2	**3**	**4**	**5**	**6**	**7-14**	**15**
Initial Installation Analysis							
Total initial outlay	$23	$23	$23	$23	$23	$23	$23
Total annual (recurring) costs	$320	$375	$375	$375	$462	$548	$721
Present value total annual (recurring)	$2,247	$2,637	$2,637	$2,637	$3,244	$3,852	$5,067
Total present value, at year 1	$2,270	$2,660	$2,660	$2,660	$3,267	$3,875	$5,090
Reinstallation Analysis — Equipment Reinstalled at Beginning of Year 11							
Total initial outlay (0.5 installation charge)	$555	$835	$835	$835	$1,196	$1,470	$2,895
Total annual (recurring) costs	$320	$375	$375	$375	$462	$548	$721
Present value total annual (recurring)	$2,247	$2,637	$2,637	$2,637	$3,244	$3,852	$5,067
Total present value, at year 11	$2,802	$3,472	$3,472	$3,472	$4,440	$5,322	$7,962
Total present value, at year 1	$1,424	$1,765	$1,765	$1,765	$2,257	$2,705	$4,047
Combining Initial Installation and Re-Installation							
Sum, present values at year 1	$3,694	$4,425	$4,425	$4,425	$5,525	$6,580	$9,137
Total Annualized Cost	**$349**	**$418**	**$418**	**$418**	**$521**	**$621**	**$863**

Source: U.S. EPA, 2016a

a – Present values and annualized costs calculated using a 7 percent discount rate. All costs are on a pre-tax basis and as of the time of compliance by complying entities.

As discussed in Chapter 10.1.2, EPA anticipates that some dental offices that do not already have an amalgam separator do not place or remove dental amalgam, and thus would incur no treatment technology-related costs from the final dental category rule. Although these offices will not incur treatment technology-related compliance costs, they will incur the cost of the One-Time Compliance Report to document that they do not use amalgam in their operations. EPA estimates this cost to be $23 for each of these offices.

In calculating the total compliance cost for the rule, these one-time reporting costs are annualized using the discount rate and number of periods for non-recurring outlays, and added to the total rule costs for offices incurring technology-related costs based on the estimated number of offices not using dental amalgam.

10.2.2 Linking Compliance Costs By Number of Chairs to Dental Offices by Revenue Range

The final step in developing compliance costs for use in the cost and economic impact analysis is to link compliance costs by number of chairs to dental offices by revenue range. As described in Chapter 10.1.1, the Economic Census reports information on dental offices by *revenue ranges*. However, EPA determined that number of chairs is the key driver of technology requirements, and thus estimated compliance requirements and costs based on the number of chairs in the office. As a result, for estimating the compliance costs incurred by dental offices *by revenue range,* it is essential to link offices *by number of chairs* to offices *by revenue range*. This information is then used to estimate the total cost of regulatory compliance across dental offices— based on numbers of offices by revenue range— and to estimate the impact of rule requirements on dental offices, based on office revenue. Ideally, this linkage would have been developed using a distribution of the number of chairs by dental office revenue range; however, EPA was not able to obtain such data. As an alternative approach, EPA identified two sources of data describing the distribution of number of chairs over all dental offices, regardless of office revenue.

- "An Economic Study of Expanded Duties of Dental Auxiliaries in Colorado" (ADA, 2009). This study is called the "ADA Colorado Study" below. Based on a survey of 154 dental offices in Colorado, it provides a distribution of number of chairs by office.
- "2009 Survey of Dental Practice: Income from the Private Practice of Dentistry" (ADA, 2010). This study, called the "ADA National Study" below, indirectly reports a distribution of number of chairs by office.

Table 10-7 summarizes the number-of-chair distributions from these sources. Although these sources do not use the same number-of-chair ranges, the summary distributions are relatively similar. For example, the ADA National Study's data distribution indicates that 56 percent of offices have four or fewer chairs and the ADA Colorado Study indicates 64 percent of offices with four or fewer chairs.

Table 10-7. Distribution of the Number of Chairs in Dental Offices

Number of Chairs in Office	Frequency	Relative Frequency	Running Total, Frequency
ADA Colorado Study, 2009			
1–2	15	9.7%	9.7%
3	39	25.3%	35.1%
4	45	29.2%	64.3%
5	22	14.3%	78.6%
6	9	5.8%	84.4%
7 or more	24	15.6%	100.0%
ADA National Study, 2010			
1–2	89	12.5%	12.5%
3–4	310	43.4%	55.9%
5–6	191	26.8%	82.6%
7 or more	124	17.4%	100.0%

Source: ADA, 2009; ADA, 2010

EPA used these distributions to estimate the number of chairs in offices that process dental amalgam by revenue range. This estimation started with the assumption that increasing the number of chairs in a dental office consistently increases office revenue.[33] Beginning with the lowest number-of-chairs range, one to two chairs, EPA assigned these offices to the lowest and then successively higher revenue ranges until the entire percentage of offices with one or two chairs was "used up." When the offices with a given number of chairs were "used up" without exhausting a specific revenue range, the available percentage of offices with that number of chairs was assigned within the revenue range assuming that offices are distributed uniformly by revenue across the revenue range. Once the revenue "break point" was reached, offices from the next higher number-of-chairs range were assigned to the remaining offices in the revenue range, and successively higher revenue ranges until that part of the chairs distribution was "used up." This process was repeated until all offices by "number of chairs" were assigned across all revenue ranges.

Table 10-8 summarizes the assignment process and results for the ADA Colorado Study and ADA National Study number-of-chair distributions. The table reports the assignment by revenue range and number of chairs for all offices, regardless of baseline status, with the exception of dental schools and military clinics. These establishments are not included in this tally because EPA possesses no information on their revenue.

[33] Exceptions to this assumption would include a dental office with exclusive clientele (i.e., an office with a small number of chairs that is in a higher revenue range). EPA did not have data to evaluate these exclusive clientele dental offices and therefore finds it reasonable to assume on a national basis that number of chairs in a dental office increases with office revenue.

Table 10-8. Number of Chairs in Dental Offices by Revenue Range

Revenue Range Values (2016$) (see Table 10-2)		Offices By Revenue Range (see Table 10-2)				With Allocation by Number of Chairs in Office				
Low	**High**	**Number of Offices**	**Percent of Total Offices**	**Running Total Percent**	**Number of Chairs**	**Number of Offices**	**Running Total**	**Percent of Total Offices**	**Running Total Percent**	**Cumulative % from ADA Distribution**
Using ADA Colorado Study Distribution										
$0	$10,491	63	0.05%	0.05%	1–2	63	63	0.05%	0.05%	9.74%
$10,492	$26,228	494	0.37%	0.42%	1–2	494	557	0.37%	0.42%	
$26,229	$52,458	1,235	0.93%	1.35%	1–2	1,235	1,792	0.93%	1.35%	
$52,459	$104,917	3,234	2.43%	3.77%	1–2	3,234	5,026	2.43%	3.77%	
$104,918	$186,092	15,413	11.57%	15.34%	1–2	7,950	12,976	5.97%	**9.74%**	
$186,093	$262,293				3	7,463	20,439	5.60%	15.34%	35.06%
$262,294	$483,513	31,153	23.38%	38.73%	3	26,275	46,714	19.72%	**35.06%**	
$483,514	$524,587				4	4,879	51,592	3.66%	38.73%	64.29%
$524,588	$913,751	45,899	34.45%	73.18%	4	34,050	85,642	25.56%	**64.29%**	
$913,752	$1,049,175				5	11,849	97,491	8.89%	73.18%	78.57%
$1,049,176	$1,415,091	30,892	23.19%	96.37%	5	7,183	104,674	5.39%	**78.57%**	
$1,415,092	$1,811,723				6	7,786	112,459	5.84%	**84.42%**	84.42%
$1,811,724	$2,622,939				7-14	15,924	128,383	11.95%	96.37%	100.00%
$2,622,940	$5,245,879	4,291	3.22%	99.59%	7-14	4,291	132,674	3.22%	99.59%	
$5,245,880	$10,491,759	474	0.36%	99.95%	7-14	474	133,148	0.36%	99.95%	
$10,491,760	Or more	73	0.05%	100.00%	7-14	73	133,221	0.05%	**100.00%**	
Total[a]		**133,221**	**100.00%**		—	**133,221**		**100.00%**		

Table 10-8. Number of Chairs in Dental Offices by Revenue Range

Revenue Range Values (2016$) (see Table 10-2)		Offices By Revenue Range (see Table 10-2)				With Allocation by Number of Chairs in Office				
Low	**High**	**Number of Offices**	**Percent of Total Offices**	**Running Total Percent**	**Number of Chairs**	**Number of Offices**	**Running Total**	**Percent of Total Offices**	**Running Total Percent**	**Cumulative % from ADA Distribution**
Using ADA National Study Distribution										
0	$10,448	63	0.05%	0.05%	1–2	63	63	0.05%	0.05%	12.46%
$10,449	$26,120	494	0.37%	0.42%	1–2	494	557	0.37%	0.42%	
$26,121	$52,242	1,235	0.93%	1.35%	1–2	1,235	1,792	0.93%	1.35%	
$52,243	$104,485	3,234	2.43%	3.77%	1–2	3,234	5,026	2.43%	3.77%	
$104,486	$231,731	15,413	11.57%	15.34%	1–2	11,580	16,606	8.69%	**12.46%**	
$231,732	$261,213				3–4	3,833	20,439	2.88%	15.34%	55.88%
$261,214	$522,427	31,153	23.38%	38.73%	3–4	31,153	51,592	23.38%	38.73%	
$522,428	$760,147	45,899	34.45%	73.18%	3–4	22,855	74,447	17.16%	**55.88%**	
$760,148	$1,044,856				5–6	23,044	97,491	17.30%	73.18%	82.63%
$1,044,857	$1,539,698	30,892	23.19%	96.37%	5–6	12,594	110,085	9.45%	**82.63%**	
$1,539,699	$2,612,141				7+	18,298	128,383	13.74%	96.37%	100.00%
$2,612,142	$5,224,283	4,291	3.22%	99.59%	7+	4,291	132,674	3.22%	99.59%	
$5,224,284	$10,448,567	474	0.36%	99.95%	7+	474	133,148	0.36%	99.95%	
$10,448,568	Or more	73	0.05%	100.00%	7+	73	133,221	0.05%	**100.00%**	
Total[a]		**133,221**	**100.00%**		—	**133,221**		**100.00%**		

Source: ADA, 2009, ADA, 2010, U.S. EPA, 2016a

a – The total 133,221 offices include the entire dental industry as reported in U.S. Census Bureau, 2012b, including those dental specialists discussed in Chapter 10.1.2 that are not subject to the rule.

10.2.3 Estimated Cost of Compliance to Dental Offices

To estimate the total nationwide cost of compliance to dental offices of the rule, EPA multiplied the estimated total annualized cost of rule compliance by the number of chairs for dental offices (see Chapter 10.1.2). EPA then added these values over the size ranges to yield the total estimated compliance cost. These calculations account for baseline compliance status (i.e., whether offices are assumed to have already installed amalgam separators). These costs are the pre-tax costs estimated to be incurred by complying offices as of the year of compliance.

EPA completed these calculations separately for the two distributions of offices by number of chairs. Table 10-9 summarizes the results from these calculations. These total compliance cost estimates include the one-time reporting costs those dental offices that do not process dental amalgam, as described in Chapter 10.2.1.

Table 10-9. Annualized Costs to Complying Dental Offices by Number of Chairs

Annualized Cost (Millions, 2016$) for Alternative Number-of-Chairs Distributions[a]		
Number of Chairs	**Colorado Survey**	**ADA Survey**
1–2 chairs	$4.7	$6.0
3 chairs	$15.2	$26.1
4 chairs	$17.5	
5 chairs	$8.6	$18.4
6 chairs	$4.5	
7-14 chairs	$14.6	$16.3
15 chairs	$0.4	$0.4
Total Costs	**$65.5**	**$67.1**

Source: U.S. EPA, 2016a

a – Present values and annualized costs are calculated using a 7 percent discount rate. All costs are on a pre-tax basis and as of the time of compliance by complying entities.

Costs are higher for the ADA National Study data distribution compared to the ADA Colorado Study data distribution because the ADA National Study data distribution indicates more higher-number-of-chair offices than does the ADA Colorado Study data distribution. For example, 44 percent of offices are estimated to have five or more chairs under the ADA National Study data distribution compared to 36 percent of offices under the ADA Colorado Study data distribution. Both estimates cover the same number of offices.

10.3 Economic Impact Of Compliance Costs

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 final rule to current (or pre-rule) dental office revenues (Chapter 10.3.1). In addition, EPA chose to examine the financial impacts of the rule using two measures that utilize the data EPA has on dental office baseline assets and estimated replacement capital costs: (1) ratio of the rule's capital costs to total dental office capital assets (Chapter 10.3.2); and (2) ratio of the rule's capital costs to annual dental office capital replacement costs (Chapter 10.3.3).

10.3.1 Cost-to-Revenue Analysis

The cost-to-revenue measure compares the annualized cost of regulatory compliance, at a 7 percent discount rate, with the revenue of regulated dental offices, and provides a screening-level assessment of the impact of compliance costs on dental offices. The cost-to-revenue measure assesses the loss in operating profit, on a constant annual cost basis, as a percentage of baseline revenue that a business would incur if *none* of the compliance costs were passed forward to customers. In using this impact measure, EPA assesses whether the compliance cost exceeds thresholds of one and three percent of revenue. This impact measure is also used in the Regulatory Flexibility Act assessment, described in Chapter 10.5 below.

EPA framed the cost-to-revenue analysis around the revenue range/number-of-chairs combinations, as developed in Table 10-8, and the total annualized compliance costs that would occur within each of these analysis combinations. Table 10-10 summarizes these analytic combinations. Note that EPA was not able to perform the cost-to-revenue impact analysis for dental schools and military clinics, as it has no revenue information for them. However, since EPA performed the cost-to-revenue analysis on a range of office sizes, EPA projects the results of this analysis would be similar for these entities.

In general, EPA assessed that cost impact analyses should be performed using after-tax costs, as these costs account for the reduction in costs to affected entities resulting from tax deductibility of the outlays, and thus provide a better indication of the financial impact of regulatory requirements on complying entities. In the cost-to-revenue analysis for the final dental category rule, EPA used costs on a pre-tax instead of after-tax basis, because the appropriate tax rates for complying entities, which are often sole proprietorships or partnerships, are not known. Using pre-tax instead of after-tax costs increases the likelihood of finding that costs exceed the one percent or three percent of revenue impact threshold.

Table 10-10. Revenue Range/Number-of-Chairs Combinations for Cost Impact Analysis

Revenue Range/Number of Chairs Combinations			Number of Offices Incurring Costs	Percent of Cost-Incurring Offices
Low	High	Number of Chairs		
Using ADA Colorado Study Distribution				
$0	$10,491	1–2	55	0.0%
$10,492	$26,228	1–2	432	0.4%
$26,229	$52,458	1–2	1,078	0.9%
$52,459	$104,917	1–2	2,824	2.4%
$104,918	$186,092	1–2	6,941	6.0%
$186,093	$262,293	3	6,516	5.6%
$262,294	$483,513	3	22,940	19.7%
$483,514	$524,587	4	4,259	3.7%
$524,588	$913,751	4	29,728	25.6%
$913,752	$1,049,175	5	10,345	8.9%
$1,049,176	$1,415,091	5	6,271	5.4%
$1,415,092	$1,811,723	6	6,798	5.8%
$1,811,724	$2,622,939	7-14	13,903	12.0%
$2,622,940	$5,245,879	7-14	3,746	3.2%
$5,245,880	$7,500,000	7-14	178	0.2%
$7,500,001	$10,491,759	7-14	236	0.2%

Table 10-10. Revenue Range/Number-of-Chairs Combinations for Cost Impact Analysis

Revenue Range/Number of Chairs Combinations			Number of Offices Incurring Costs	Percent of Cost-Incurring Offices
Low	High	Number of Chairs		
$10,491,760	Or more	7-14	64	0.1%
Total			**116,313**	**100.0%**
Using ADA National Study Distribution				
$0	$10,491	1–2	55	0.0%
$10,492	$26,228	1–2	432	0.4%
$26,229	$52,458	1–2	1,078	0.9%
$52,459	$104,917	1–2	2,824	2.4%
$104,918	$223,156	1–2	10,110	8.7%
$223,157	$262,293	3–4	3,347	2.9%
$262,294	$524,587	3–4	27,200	23.4%
$524,588	$785,800	3–4	19,954	17.2%
$785,801	$1,049,175	5–6	20,119	17.3%
$1,049,176	$1,690,745	5–6	10,995	9.5%
$1,690,746	$2,622,939	7-14	15,976	13.7%
$2,622,940	$5,245,879	7-14	3,746	3.2%
$5,245,880	$7,500,000	7-14	178	0.2%
$7,500,001	$10,491,759	7-14	236	0.2%
$10,491,760	Or more	7-14	64	0.1%
Total			**116,313**	**100.00%**

Source: U.S. EPA, 2016a

Costs of compliance were assigned to each revenue range/number-of-chairs combination and then assessed relative to the low and high revenue values of a revenue range to determine whether offices within the revenue range would incur costs exceeding a given percent of revenue threshold. For each revenue range/number-of-chairs combination and a given percent of revenue threshold — i.e., one or three percent — EPA evaluated three cases:

1. If the calculated cost-to-revenue percentage is less than the threshold value at the low end of the revenue range, then EPA assessed that *none* of the dental offices in that revenue range would incur costs exceeding the given percent of revenue threshold.

2. If the calculated cost-to-revenue percentage exceeds the threshold value at the high end of the revenue range, then EPA assessed that *all* of the dental offices in that revenue range would incur costs exceeding the given percent of revenue threshold.

3. If neither of the two prior conditions are met, this indicates that *some, but not all,* of the offices in the revenue range would exceed the percent of revenue threshold. To determine the number of offices exceeding the given percent of revenue threshold, EPA calculated the "break-even" revenue value for a given compliance cost and percent of revenue threshold, by dividing the compliance cost value by the given percent of revenue threshold. This break-even value is the revenue value at which compliance cost equals the percent of revenue threshold; offices with revenue below the break-even value will incur costs exceeding the given percent of revenue threshold, while offices with revenue above it will incur costs below the percent of revenue threshold. To calculate the number of offices with costs exceeding the

percent of revenue threshold, EPA assumed that offices are distributed uniformly within the revenue range and calculated the fraction of offices below the break-even value as follows:

$$\text{Fraction exceeding threshold} = (RVbe - RVmin) \div (RVmax - RVmin)$$

Where:

$RVbe$	=	Break-even revenue
$RVmin$	=	Minimum value in revenue range
$RVmax$	=	Maximum value in revenue range

EPA tallied the estimated fraction of offices within each number-of-chairs/revenue range combination that exceed a given percent of revenue threshold. Results were developed separately for both the ADA Colorado Study and ADA National Study chairs-by-office distributions and accounting for technology-in-place status.

Because EPA does not have detailed data on baseline financial conditions of dental offices, the effect of the pretreatment standard on dental office income statements and balance sheets cannot be measured by a closure analysis (as is EPA's more typical practice for analyzing economic achievability). 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. Still, the 2012 Economic Census reports that approximately 557 offices of the approximately 133,221 total offices had revenue of less than $25,000 (2012 dollar basis; see Table 10-1). 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:

- A low-revenue office could be a single-dentist and/or part-time business that provides services as a subcontractor on an independent fee-for-service basis, such as dental hygiene, in a general service dental office that is 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 the final 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. Alternatively, 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 that some of these very low-revenue offices could be non-profit groups that provide pay-as-you-can or free services to 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 very low revenue establishments could be non-viable as for-profit businesses, if they are attempting to operate as general service dental practices. This reasoning is based on EPA's assessment of the ongoing outlay required for replacement of existing dental office capital equipment, which was performed for the third part of the cost impact analysis (Chapter 10.3.3, below). Specifically, in this analysis, EPA estimated that one- to two-chair offices would incur capital replacement costs of approximately $25,400 per year (the estimated annual cost of keeping equipment in good working order; 2016 dollar basis). This outlay would exceed the annual revenue of the business in the below-$25,000 revenue range. Accordingly, these offices may not be operating viably as general service dental offices.

Given these considerations, EPA performed the cost-to-revenue analysis on two bases:

- Excluding the low-revenue offices (below $25,400 revenue) from the cost-to-revenue analysis.
- Including the low-revenue offices in the cost-to-revenue analysis.

For the rest of the economic analysis chapter, EPA refers to the low-revenue offices as "baseline set-aside offices."

Following the methodology outlined above, EPA estimated the occurrence of cost-to-revenue exceeding the one and three percent of revenue thresholds for the final rule for the ADA Colorado Study and ADA National Study chairs-by-office distributions. As described above, EPA accounted for the number of offices estimated to have already installed amalgam separator technology, and the resulting compliance cost for these cases, in the cost-to-revenue calculations. For offices that certify that they do not place or remove amalgam – and have a one-time certification cost only – EPA assumed that costs would be less than 1 percent of revenue.

Table 10-11 and Table 10-12 summarize the results from this analysis. Table 10-11 reports the results by technology-in-place status; Table 10-12 reports the results by number-of-chair ranges. These findings are the same for both the ADA National Study and ADA Colorado Study chairs-by-office distributions.

With the *baseline set-aside offices* excluded from the analysis, EPA estimates that 808 dental offices would incur costs exceeding one percent of revenue, representing 0.7 percent of dental offices expected to incur costs under the final regulation. No offices incur costs exceeding three percent of revenue. With the *baseline set-aside offices* included in the analysis, EPA estimates that 1,217 dental offices would incur costs exceeding one percent of revenue, representing 1.0 percent of dental offices expected to incur costs under the final rule; 174 offices are estimated to incur costs exceeding three percent of revenue, representing 0.1 percent of offices expected to incur costs under the final rule.

Of note, all of the instances in which the cost-to-revenue impact value exceeds one or three percent occur among dental offices in revenue ranges below the small business revenue threshold of $7.5 million. This finding is relevant for Chapter 10.5.

Table 10-11. Cost-to-Revenue Analysis Impact Summary[a]

Offices with Cost Exceeding 1 Percent of Revenue				Offices with Cost Exceeding 3 Percent of Revenue			
Technology -In-Place	No-Tech-in-Place	Total	Percentage[b]	Technology -In-Place	No-Tech-in-Place	Total	Percentage[2]
Excluding Baseline Set-Aside Offices from Analysis							
156	652	808	0.7%	0	0	0	0.0%
Including Baseline Set-Aside Offices in Analysis							
347	871	1,217	1.0%	35	139	174	0.1%

Source: U.S. EPA, 2016a

a – Number of offices with costs exceeding 1 percent and 3 percent of revenue includes those offices with some technology-related costs, and excludes a) offices not subject to the rule, and b) dental schools and military clinics for which EPA does not have revenues. EPA assumes that offices with reporting costs only (those that certify that they do not place or remove amalgam) will have costs less than 1% of revenues.

b – Percentages of affected offices are calculated as a fraction of total offices estimated to incur any costs under the dental category rule for which revenue data are available (116,313 offices).

Table 10-12. Cost-to-Revenue Analysis Impact Summary by Number of Chairs[a]

Number of Chairs	Excluding Baseline Set-Aside Offices from Analysis				Including Baseline Set-Aside Offices in Analysis			
	Costs >1% Rev.		Costs >3% Rev.		Costs >1% Rev.		Costs >3% Rev.	
	Number	%	Number	%	Number	%	Number	%
1–2 chairs	808	6.3%	0	0.0%	1,217	9.4%	174	1.4%
3 chairs	0	0.0%	0	0.0%	0	0.0%	0	0.0%
4 chairs	0	0.0%	0	0.0%	0	0.0%	0	0.0%
5 chairs	0	0.0%	0	0.0%	0	0.0%	0	0.0%
6 chairs	0	0.0%	0	0.0%	0	0.0%	0	0.0%
7-14 chairs	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total	808	0.7%	0	0.0%	1,217	1.0%	174	0.1%

Source: U.S. EPA, 2016a

a – Percentages of affected offices are calculated as a fraction of total offices estimated to incur any costs under the dental category rule for which revenue data are available (116,313 offices). EPA assumes that offices with reporting costs only (those that certify that they do not place or remove amalgam) will have costs less than 1% of revenues.

From this analysis, due to the small percentage of offices potentially incurring costs over one percent or three percent of revenue, EPA finds that the final rule would not have a material adverse impact on the dental office sector.

10.3.2 Ratio of the Final Rule's Capital Costs to Total Dental Office Capital Assets

From the preceding analysis, EPA found that the final rule will have minimal impact on operating finances given that less than one percent of dental offices may incur annualized compliance costs exceeding one or three percent of revenue. Given this finding, it is possible that the more material impact of the final dental category rule could result from the need of dental offices to finance the initial outlays required for rule compliance — in particular, technology purchase and installation. Accordingly, EPA undertook two additional analyses of potential impact based on the requirement to finance the initial outlay. The first of these, presented in this chapter, examines the initial outlay in relation to the baseline value of assets on the balance sheet of dental office businesses. The second analysis, presented in Chapter 10.3.3, examines the initial outlay in relation to the estimated steady state outlays for capital replacement for the dental office business. The steady state capital replacement outlay represents a value dental offices may reasonably expect to spend in the periodic outlays to replace and/or upgrade dental office capital equipment. For both tests, EPA assumed that a low ratio implies limited impact on dental offices' ability to finance the initial spending on compliance capital costs of the final rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting.

For the analysis of capital outlays in relation to baseline assets, EPA relied on data from Risk Management Association (RMA)[34] to estimate the baseline assets of dental offices by revenue range. Specifically, EPA used asset to sales ratios for the dental office sector to estimate an asset value for the minimum and maximum revenue values for each of the revenue range/number of chairs combinations as analyzed in the preceding chapter. Each revenue range/number of chairs combination then has a minimum and maximum asset value for use in the *capital outlay to baseline asset value* analysis. The RMA data have the limitation that they may not be fully representative of all dental offices, because they only represent dental offices that are successful borrowers. Hence, the RMA data may underrepresent offices that are not financially healthy. This would cause EPA's finding of impact to understate the actual impacts.

Using the same approach to assigning compliance requirements to the revenue range/number-of-chairs analysis combinations, as described in Chapter 10.3.1, EPA then assigned the *initial outlays only* to the revenue range/number-of-chairs analysis combinations. The values of initial outlays were then compared to the minimum and maximum values of each revenue range/number-of-chairs analysis combination to assess the potential capital outlay/financing burden. In the same way as described for the preceding cost-to-revenue analysis, the capital outlay to baseline asset value analysis accounted for whether offices have already installed amalgam separator technology and also used the alternative number of chairs by office distributions (ADA Colorado Study and ADA National Study). Also, EPA performed this analysis both including and excluding the *baseline set-aside offices*. For the analysis including the baseline set-aside offices, EPA assumed a minimum revenue value of $5,000 (and the corresponding baseline assets value) for the lowest revenue range, to prevent division by zero.

Table 10-13 reports the findings from this analysis, specifically the average outlay-to-assets ratio values by operating size (number of chairs), and the weighted average of the outlay-to-assets ratio across the number-of-chairs ranges. As with the cost-to-revenue impact analysis, EPA did not perform this analysis for dental schools and military clinics, as it has no financial data on which to base the analysis. However, since EPA performed this analysis on a range of office sizes, EPA projects that the results of this analysis would be similar for these entities.

[34] RMA 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.

Table 10-13. Initial Compliance Outlay as a Percentage of Baseline Assets

Number of Chairs	Technology-in-Place		No Technology-in-Place	
	Low	High	Low	High
Excluding Baseline Set-Aside Offices from Analysis				
1–2 chairs	0.1%	0.0%	2.4%	1.2%
3 chairs	0.0%	0.0%	0.9%	0.5%
4 chairs	0.0%	0.0%	0.6%	0.4%
5 chairs	0.0%	0.0%	0.3%	0.2%
6 chairs	0.0%	0.0%	0.3%	0.2%
7-14 chairs	0.0%	0.0%	0.2%	0.1%
Total	0.0%	0.0%	0.7%	0.4%
Including Baseline Set-Aside Offices in Analysis				
1–2 chairs	0.1%	0.0%	3.0%	1.5%
3 chairs	0.0%	0.0%	0.9%	0.5%
4 chairs	0.0%	0.0%	0.6%	0.4%
5 chairs	0.0%	0.0%	0.3%	0.2%
6 chairs	0.0%	0.0%	0.3%	0.2%
7-14 chairs	0.0%	0.0%	0.2%	0.1%
Total	0.0%	0.0%	0.7%	0.4%

Source: U.S. EPA, 2016a

In both baseline set-aside scenarios (excluding or including these offices in the analysis), the initial capital costs to total capital assets values are low, with an average value of 0.4 percent to 0.7 percent for no-technology-in-place offices and 0 percent for the technology-in-place offices. EPA finds these results to indicate that dental offices should not encounter difficulty in financing the increase in assets that would result from installing amalgam separators.

10.3.3 <u>Ratio of the Final Rule's Capital Costs to Annual Dental Office Capital Replacement Costs</u>

As another test of the potential burden of financing the initial outlays for rule compliance, EPA compared the initial outlay with estimated steady state outlays for capital replacement for the dental office business. As stated above, the steady state capital replacement outlay represents a value dental offices may reasonably expect to spend in the periodic outlays to replace and/or upgrade dental office capital equipment. EPA assumed a low ratio implies limited impact on dental offices' ability to finance the initial spending on capital costs of the final rule. A high ratio may still allow costs to be financed but could imply a need to change capital planning and budgeting.

For this comparison, 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 and Child Oral Health Resource Center at Georgetown University (Georgetown University, 2003). This publication reports overall costs in broad categories of major and small items for two specific number-of-chair offices (three chairs and six chairs) and provides additional detail on specific equipment needs for the six-chair office, including the estimated service life for the various items of equipment. EPA worked with these data in several ways to develop an estimate of the steady state capital replacement outlay:

- EPA used the detailed cost and service life information for the six-chair office to develop a profile of startup outlays by service life and developed percentages of total startup outlay by service life for two broad categories of major and small items (see Table 10-14).

- EPA used the aggregate cost information by the major and small item categories, for the three- and six-chair offices, to estimate startup outlays for other number-of-chair offices to be accounted for in the analysis. EPA interpolated between and/or extrapolated from the three- and six-chair office values to develop the startup cost estimates for the other chair size offices, including additional analysis for the eight- and nine-chair offices. EPA adjusted some of the values for the one- or two-chair office to reflect the fact that some equipment needs have a minimum number and/or cost regardless of how few chairs are in the office. The first chapter of Table 10-15, "Initial Outlays" by major and small items, reports the results from this step (EPA assumed initial compliance outlay for eight- and nine-chair offices is the same as a seven-chair office).

- EPA allocated the broad components of cost — major and small items — for each office size, into the specific service life categories based on the service life percentages reported in Table 10-14. The second chapter of Table 10-15, "Initial Outlays by Equipment Life Category," reports the results from this step.

- To estimate a steady-state replacement outlay, EPA divided the estimated outlays for each service life category by the number of years for the service life category, and summed these values over the service life categories for each of the number-of-chair office specifications. EPA recognizes that outlays for capital replacement and/or refurbishment will not generally occur on a uniform basis from year to year, but on average, over a period of several years, the annual replacement and/or refurbishment outlay should be approximately this "steady state" value. The third chapter of Table 10-15, "Steady State Annual Replacement Outlay, by Equipment Life Category," reports the results from this step.

Table 10-14. Cost of Dental Equipment for Six-Chair Office by Equipment Life

Useful Life Category	Value by Service Life Category (2016$)[a]			
	Major Items	Percent	Small Items	Percent
3	$0	0.0%	$25,200	21.5%
5	$66,562	21.5%	$0	0.0%
10	$100,702	32.6%	$91,811	78.5%
12	$8,718	2.8%	$0	0.0%
15	$133,055	43.1%	$0	0.0%
Total	$309,037	100.0%	$117,011	100.0%

Source: U.S. EPA, 2016a; based on 6-chair office specifications from Georgetown University, 2003.
a – All costs updated to 2016$ using the Implicit Price Deflators for Gross Domestic Product (U.S. BLS, 2016).

Table 10-15. Initial and Annual Replacement Outlay for Startup Dental Office by Number of Chairs (2016$)[a]

	Number of Chairs							
	1–2	3	4	5	6	7	8	9
Initial Outlays								
Major items	$178,611	$235,748	$279,003	$322,257	$365,512	$408,766	$452,021	$471,537
Small items	$42,185	$66,458	$86,792	$107,126	$127,460	$147,794	$168,128	$187,698
Total	**$220,796**	**$302,206**	**$365,795**	**$429,383**	**$492,972**	**$556,560**	**$620,149**	**$659,235**
Initial Outlays by Equipment Life Category								
3	$9,085	$14,313	$18,692	$23,071	$27,450	$31,830	$36,209	$40,424
5	$38,470	$50,777	$60,093	$69,409	$78,726	$88,042	$97,359	$101,562
10	$91,302	$128,966	$159,015	$189,065	$219,114	$249,164	$279,214	$300,929
12	$5,039	$6,651	$7,871	$9,091	$10,311	$11,531	$12,752	$13,302
15	$76,901	$101,501	$120,124	$138,747	$157,370	$175,993	$194,616	$203,019
Total	**$220,796**	**$302,206**	**$365,795**	**$429,383**	**$492,972**	**$556,560**	**$620,149**	**$659,235**
Steady State Annual Replacement Outlay, by Equipment Life Category								
3	$3,028	$4,771	$6,231	$7,690	$9,150	$10,610	$12,070	$13,475
5	$7,694	$10,155	$12,019	$13,882	$15,745	$17,608	$19,472	$20,312
10	$9,130	$12,897	$15,902	$18,906	$21,911	$24,916	$27,921	$30,093
12	$420	$554	$656	$758	$859	$961	$1,063	$1,109
15	$5,127	$6,767	$8,008	$9,250	$10,491	$11,733	$12,974	$13,535
Total	**$25,399**	**$35,144**	**$42,815**	**$50,486**	**$58,157**	**$65,829**	**$73,500**	**$78,523**

Source: U.S. EPA, 2016a

a – All costs updated to 2016$ using the Implicit Price Deflator for Gross Domestic Product (U.S. BLS, 2016).

As the final step in this analysis, EPA compared the estimated total initial outlay for the final dental category rule to the estimated steady state annual replacement outlay values, from Table 10-15. Table 10-16 reports the results from this comparison. As shown in Table 10-16, the values for initial compliance outlay as a percentage of replacement outlay are quite low, ranging from 2.0 percent to 2.8 percent, with a weighted average of 2.4 percent across all number-of-chair ranges.

Table 10-16. Comparing Total Initial Compliance Outlay to Steady State Annual Replacement Outlay by Number of Chairs (Chapter 10.3.3; 2016$)

	Number of Chairs								
	1–2	3	4	5	6	7	8	9	Weighted Average
Initial compliance outlay	$695	$996	$996	$996	$1,357	$1,672	$1,672	$1,672	$1,109
Baseline annual replacement outlay	$25,399	$35,144	$42,815	$50,486	$58,157	$65,829	$73,500	$78,523	$46,523
Initial compliance outlay as percentage of replacement outlay	2.7%	2.8%	2.3%	2.0%	2.3%	2.5%	2.3%	2.1%	**2.4%**

Source: U.S. EPA, 2016a

Table 10-17. Comparing Total Initial Compliance Outlay to Initial Outlay by Number of Chairs (Chapter 10.3.4; 2016$)

	Number of Chairs								
	1–2	3	4	5	6	7	8	9	Weighted Average
Initial compliance outlay	$695	$996	$996	$996	$1,357	$1,672	$1,672	$1,672	$1,109
Initial outlay	$220,796	$302,206	$365,795	$429,383	$492,972	$556,560	$620,149	$659,235	$396,319
Initial compliance outlay as percentage of office startup costs	0.3%	0.3%	0.3%	0.2%	0.3%	0.3%	0.3%	0.3%	**0.3%**

Source: U.S. EPA, 2016a

10.3.4 Economic Impact for New Sources

EPA assessed whether the pretreatment standard for new sources would impose a barrier to entry. To perform this analysis, EPA relied on data describing the equipment needs and costs for starting a dental office as compiled in the *Safety Net Dental Clinic Manual*, prepared by the National Maternal and Child Oral Health Resource Center at Georgetown University. EPA calculated the initial outlay to start a dental office as shown above in Table 10-15. EPA then compared the initial compliance cost for dental offices as estimated in Chapter 10.2 to these startup values. This comparison demonstrates that the amalgam separator capital costs would represent only 0.2 percent to 0.3 percent of the cost of starting a dental office and, therefore, do not pose a barrier to entry (see Table 10-17 above).

10.4 Social Cost Of The Final Dental Category Rule

The previous chapters reviewed the estimated costs of the final dental category rule to dental offices and assessed the potential impact of the final rule on these offices. This chapter reviews the costs of the final dental category rule from the standpoint of cost to society, or social cost. The assessment of social cost builds from the estimated costs of regulatory compliance, as described in Chapter 10.2.1, but differs from the assessment of costs to dental offices in the following respects:

- The assessment of cost of compliance to dental offices used a discount rate of 7 percent for developing present and annualized values. As described previously, the 7 percent discount rate represents an estimated opportunity cost of capital to society, on a pre-tax, constant dollar basis. The analysis of social cost uses an additional discount rate, 3 percent, which represents a societal rate of time preference — the rate at which society desires to be compensated for deferring consumption from one year to the next. Social costs are presented on the basis of both 3 and 7 percent discount rates.

- The assessment of cost of compliance to dental offices included only the costs incurred by these offices. The assessment of social cost includes these costs of compliance, but also includes an additional cost that will be incurred by society, namely the cost to permitting authorities for administering the final dental category rule.

- The assessment of cost of compliance to dental offices developed present values and annualized costs as of the time at which dental offices would comply with the rule's requirements, regardless of the specific calendar year in which compliance would occur. The assessment of social cost develops present and annualized values as of the expected year of rule promulgation, 2016, and the compliance period three years following promulgation, in 2019. Specifically, using the analytic convention outlined previously for the assessment of compliance costs to dental offices, costs are first developed over an assumed 20-year compliance period, which reflects initial installation of compliance equipment at the first year of compliance, and then reinstallation at the 11th year of the 20-year analysis period. These costs are discounted to the year of compliance and then annualized over the 20 years of rule compliance. These present and annualized values, which are assumed to be as of 2019, or the first year of required compliance, are then discounted an additional three years to 2016, the year of rule promulgation.

In assessing social costs, EPA assumed that the regulation would result in no change in the total quantity of services provided by the dental industry. Thus, the social cost analysis includes no loss in economic surplus to society due to contraction of dental industry output, and the social cost estimate includes only the resource costs of compliance and rule administration. Given that the rule's total annualized costs are estimated to represent less than 0.1 percent of the total value of dental services,[35] EPA assesses that the assumption of no change in industry output is reasonable.

10.4.1 Cost of Compliance on Social Cost Basis

For the analysis of social cost, compliance costs are developed on the same basis as described in Chapter 10.2, with the exceptions, as noted above, that costs are calculated on a present value and annualized cost basis as of the year of rule promulgation, 2016, and using 3 percent and 7 percent discount rates. Table 10-18 summarizes these cost values for the final rule by the alternative number-of-chair distributions.

Table 10-18. Compliance Costs on a Social Cost Basis for Final Dental Amalgam Rule

Annualized Cost (Millions, $2016) as of 2016, Year of Rule Promulgation				
	Using 3 Percent Discount Rate		Using 7 Percent Discount Rate	
	Colorado Survey	ADA Survey	Colorado Survey	ADA Survey
Compliance cost	$58.6	$60.0	$53.5	$54.8

Source: U.S. EPA, 2016a

10.4.2 Administrative Costs

As described above, these costs are calculated for the year of rule promulgation, 2016, as $814,000 at a 7 percent discount rate and $785,000 at a 3 percent discount rate. As discussed in Chapter 1.2.2, the Control Authority could be the publicly owned treatment works (POTW), the state, or U.S. EPA Region. EPA estimated the annual recordkeeping costs for the following Control Authorities:

- 403.10(e) States: 5 Control Authorities;
- POTWs: 1,600 Control Authorities;[36]
- Approved Pretreatment States (minus the 403.10(e) States): 31 Control Authorities; and

[35] Approximately $110 billion, based on 2012 Economic Census data (U.S. Census Bureau, 2012a) and updated to 2016 dollars using Implicit Price Deflators for Gross Domestic Product (U.S. BLS, 2016).

[36] Estimated approved Control Authority POTWs nationwide via U.S. EPA, 2011.

- U.S. EPA Regions: 9 Control Authorities.[37]

EPA used a labor rate estimate of $58.56/hour[38] for these Control Authorities and an appropriate time estimate for each activity mentioned above (e.g., recordkeeping) (U.S. EPA, 2016d). Annual costs were assumed to meet a five-year compliance schedule. Administrative costs were assumed over a three-year period, because of the pretreatment standards program information collection request (ICR) that is completed every three years (U.S. EPA, 2011).

10.4.3 Total Social Cost

Table 10-19 summarizes the estimated total social cost for the final dental category rule, including both compliance costs and administrative costs. Costs are reported for the 3 percent and 7 percent discount rates.

Table 10-19. Summary of Social Cost for Final Dental Category Rule

Annualized Cost (Millions, $2016) as of Year of Rule Promulgation				
	Using 3 Percent Discount Rate		Using 7 Percent Discount Rate	
Cost Category	Colorado Survey	ADA Survey	Colorado Survey	ADA Survey
Compliance cost	$58.6	$60.0	$53.5	$54.8
Cost to permitting authorities	$0.8	$0.8	$0.8	$0.8
Total social cost	**$59.4**	**$60.8**	**$54.3**	**$55.6**

Source: U.S. EPA, 2016a

10.5 Regulatory Flexibility Act Assessment

As part of the cost and economic impact assessment for the final dental category rule, EPA considered the potential impact on small entities in the dental office business. Of key concern in this assessment is whether the final dental category rule could cause a significant impact on a substantial number of small entities (SISNOSE).

As reported previously, the Small Business Administration criterion for defining a small entity in the dental office sector (NAICS 621210) is $7.5 million in revenue. In the same way as for the previous general economic impact analysis, EPA framed its small entity analysis around establishments, or individual dental offices, instead of using the firm. Because nearly 98 percent of dental office firms are single unit businesses (U.S. Census Bureau, 2012b), there is minimal difference in performing this analysis at the level of the dental office compared to the dental firm.

To estimate the number of number of small business dental offices, EPA relied on dental office counts from the Economic Census, as used elsewhere in this analysis. EPA first segmented the Economic Census revenue range that contains the small business criterion into office counts that are above and below the criterion, assuming that offices are uniformly distributed across this revenue range according to revenue size. This segmentation applies to less than one percent of

[37] All states in Region 4 have approved pretreatment programs, so the state has the approval authority.

[38] Based on the Metal Products and Machinery 150 POTW Study (1999$: U.S. EPA, 2000). EPA updated to 2016$ using the Bureau of Labor Statistics Cost Index for State and Local Government Public Administration.

the total number of small businesses in the dental office sector, so the error introduced by assuming a uniform distribution is minor, at most, in the overall analysis.

In addition, as described previously, EPA also estimated that some dental offices subject to the rule *do not process dental amalgam,* and thus will incur only one-time reporting costs pursuant to the dental category rule.

EPA estimated that approximately 132,878 dental offices are small businesses and that approximately 116,014 of these small business dental offices could incur costs under the rule. Because the number of small business dental offices that process amalgam is only 707 offices less than the total dental offices subject to the rule (116,720), and cost-to-revenue impacts above the thresholds are located in the lower revenue ranges, there is no difference between the cost-to-revenue analysis performed for all dental offices and that performed for small entities.

To assess the potential for *significant impact* on these small businesses, EPA relied on the method of the cost-to-revenue impact analysis as presented in Chapter 10.3.1, which used one and three percent of revenue thresholds as impact measures. As described in that chapter, EPA performed this analysis on two bases:

- Excluding the *baseline set-aside* offices from the cost-to-revenue analysis.
- Including the *baseline set-aside* offices in the cost-to-revenue analysis.

Table 10-20 summarizes the results for small entities from this analysis.

Table 10-20. Cost-to-Revenue Impact Analysis for Small Entities[a]

Offices with Cost Exceeding 1 Percent of Revenue				Offices with Cost Exceeding 3 Percent of Revenue			
Technology-In-Place	No-Tech-in-Place	Total	Percentage	Technology-In-Place	No-Tech-in-Place	Total	Percentage
Excluding Baseline Set-Aside Offices from Analysis							
156	652	808	0.7%	0	0	0	0.0%
Including Baseline Set-Aside Offices in Analysis							
347	871	1,217	1.0%	35	139	174	0.2%

Source: U.S. EPA, 2016a

a – Results are the same for both the ADA National and Colorado distributions of chairs by office.

As shown in Table 10-20, with the *baseline set-aside offices* excluded from the analysis, EPA estimates that 808 dental offices would incur costs exceeding one percent of revenue.[39] These offices represent 0.7 percent of the small business offices estimated to incur costs under the dental category rule. EPA estimates that no small entities would incur costs exceeding three percent of revenue for the rule.

With the *baseline set-aside offices* included in the analysis, EPA estimates that 1,217 dental offices would incur costs exceeding one percent of revenue. These offices represent 1.0 percent of small business offices estimated to incur costs under the final dental category rule. EPA estimates that 174 dental offices would incur costs exceeding three percent of revenue,

[39] These findings do not vary by distribution of chairs by office.

representing 0.2 percent of small business offices estimated to incur costs under the final dental category rule.

From this analysis, given the very small percentage of small business dental offices potentially incurring costs exceeding the one percent and three percent of revenue thresholds, EPA estimates that the final dental category rule would not impose a significant impact on a substantial number of small entities (SISNOSE).

10.6 REFERENCES

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Chapter 11
Pollutant Reduction Estimates

The final rule establishes pretreatment standards based on proper operation and maintenance of one or more amalgam separators compliant with the ISO 11143 standard (or its equivalent) and two best management practices (BMPs). EPA's pollutant reduction methodology assumes dental offices will use the required BMPs in combination with amalgam separators that meet the 2008 ISO 11143 standard, the technology basis, to comply with the final rule.

EPA does not have office-specific discharge data for the approximately 117,000 dental offices potentially subject to the final rule. Instead, EPA modeled the baseline, pre-rule discharges of mercury and other metals 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 (and other pollutant) loadings by dividing the total number of annual procedures by the total number of dentists performing these procedures.[40] This is the same approach and data that EPA presented in its *Health Services Industry Detailed Study* (U.S. EPA, 2008). EPA did not receive comments on this part of the detailed study that would cause EPA to reconsider its approach, and therefore, EPA did not change the overall methodology. The following chapters describe the methodology in more detail.

11.1 National Estimate Of Annual Pollutant Loadings From Dental Offices

This chapter describes the methodology used to estimate national baseline pollutant loadings generated at dental offices and discharged to publicly owned treatment works (POTWs) and to surface waters.

11.1.1 National Estimate of Annual Mercury in Dental Office Wastewater

First, EPA estimated the amount of mercury potentially generated nationwide through amalgam restorations (placements). EPA's main source of the data underlying all of the estimates related to restorations is Vandeven and McGinnis, 2005. EPA estimated that 71 million restorations are performed at dental offices annually and that these restorations require one amalgam capsule per restoration.

Dental amalgam capsules used for restorations contain approximately 450 milligrams (mg) of mercury. When placed in the patient's mouth, approximately 75 percent of the amalgam is used (340 mg of mercury), with the remaining amount recycled or discarded as gray bag waste. Of the amount used for restoration, an estimated 9 percent of the amalgam (30.6 mg of mercury) enters the dental office wastewater as carvings and filings or other waste (Vandeven and McGinnis, 2005). From these data, EPA estimated that dental offices generate a total of 2.4

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

tons of mercury nationwide[41] in their wastewaters from restorations (U.S. EPA, 2016). Table 11-1 presents how mercury waste is generated at dental offices during amalgam restorations.

Table 11-1. Mercury Waste Generation from the Restoration of Dental Amalgam

Process Description	Total Mercury	Mercury used for Filling	Waste Mercury	Waste Disposal
Amalgam Restoration *71 million procedures per year*	450 milligrams (mg) per capsule	340 mg (75% of total mercury)	31 mg (9% of filling mercury) – carvings and filings during procedure	Rinsed into wastewater drain *2.4 tons per year from all procedures*
		110 mg (25% of total mercury) remains in capsule		Recycled or discarded as gray bag waste

Sources: U.S. EPA, 2016; Vandeven and McGinnis, 2005.

Second, EPA modeled mercury generation from amalgam removals. As with restorations, EPA's main source of the data underlying all of the estimates related to amalgam removals is Vandeven and McGinnis, 2005. The removal rate of dental amalgam fillings is 710 removals per general dentist each year and 440 removals per specialty dentist each year (Vandeven and McGinnis, 2005). Based on 2015 data, there are 195,722 total dentists: 79 percent general dentists and 21 percent specialty dentists (ADA, 2016). EPA assumed that 39 percent of general dentists place or remove amalgam based on type of specialty practice (ADA, 2016; U.S. EPA, 2016). Based on this information, EPA estimates that approximately 117 million amalgam removals occur each year (U.S. EPA, 2016).

Dental amalgam removed from patients contains approximately 300 mg of mercury per filling. An estimated 90 percent of the amalgam enters the dental office wastewater (270 mg of mercury per filling), with the remainder lost as air particulates from grinding or handled as dry waste (i.e., gray bagged). EPA estimated dental offices generate 34.8 tons of mercury in their wastewaters from amalgam filling removals each year[42] (U.S. EPA, 2016). Table 11-2 presents how mercury waste is generated at dental offices during amalgam removals.

Table 11-2. Mercury Waste Generation from the Removal of Dental Amalgam

Process Description	Total Mercury	Waste Mercury	Waste Disposal
Amalgam Removal *117 million procedures per year*	300 milligrams (mg) per removed filling	270 mg (90% of total mercury)	Rinsed into wastewater drain *34.8 tons per year from all procedures*
		30 mg (10% of total mercury)	Dry waste disposal/gray bag waste or air particulates

Sources: U.S. EPA, 2016; Vandeven and McGinnis, 2005.

[41] 71 million restorations times 31 mg per filling.

[42] 117 million amalgam filling removals times 270 mg per removal.

Summing the total mercury loading from the annual number of restorations and removals, EPA estimated dental offices generate 37.2 tons of mercury annually as part of dental office wastewaters, see Table 11-3.

Table 11-3. Annual Untreated Mercury Generation from the Restoration and Removal of Dental Amalgam

Description	Number of Procedures	Mercury in Dental Office Wastewater per Procedure	Mercury in Dental Office Wastewater (Untreated)	Notes
Amalgam Restorations	71 million	31 milligrams (mg)	2.4 tons (U.S.)	Estimate mercury entering wastewater based on number of restoration procedures. Amalgam capsule contains 450 mg of mercury. Assume 75 percent of the capsule is used for restoration (340 mg). During placement, 9 percent of the mercury (31 mg) is rinsed into wastewater drain as carvings or filings.
Amalgam Removals	117 million	270 mg	34.8 tons (U.S.)	Estimate by number of general dentists and specialists who perform removals and average number of removals per dentist and per specialist. Assume 90 percent of mercury removed (270 mg) is part of the dental office wastewater.
TOTAL			**37.2 tons**	

Sources: U.S. EPA, 2016; Vandeven and McGinnis, 2005.

11.1.2 National Estimate of Annual Baseline Mercury Discharges from Dental Offices to POTWs

EPA estimated that within the 116,719 dental offices potentially subject to the final rule, 13,685 offices do not place or remove amalgam and therefore do not generate amalgam wastewater (Chapter 10.1.2). Therefore, the remaining 103,034 offices collectively generate 37.2 tons of mercury in their wastewaters. This equates to 0.72 pounds per dental office. However, as explained earlier, some dental offices currently employ treatment technologies that will reduce this mercury prior to discharge. EPA assumed the following with respect to current technologies in place:

- Twenty percent use chair-side traps only (Vandeven and McGinnis, 2005): 20,607 dental offices.
- 48,292 dental offices use amalgam separators (U.S. EPA, 2016).
- The remaining 34,135 dental offices use chair-side traps and vacuum filters.

The mercury removal efficiency of the chair-side trap is 68 percent, and the mercury removal efficiency of the chair-side trap plus vacuum filter is 78 percent (Vandeven and McGinnis, 2005). After accounting for mercury reductions achieved through existing chair-side traps, vacuum filters, and amalgam separators, as appropriate, EPA estimated that the approximately 55,000 dental offices without amalgam separators collectively discharge a total of

10,200 pounds (5.09 tons) of mercury to POTWs per year. The approximately 48,300 dental offices with amalgam separators collectively discharge approximately 54 pounds (0.027 tons) of mercury to POTWs per year. Thus, EPA calculated the current nationwide annual baseline loading of mercury discharged to POTWs from dental offices to be 5.12 tons, out of a total of the 37.2 tons originally generated (U.S. EPA, 2016).

Table 11-4 summarizes the use and mercury removal efficiencies of wastewater treatment technologies at dental offices.

Table 11-4. Dental Office Use and Mercury Removal Efficiency by Treatment Technology

Treatment Technology	Number of Dental Offices	Removal Efficiency for Total Mercury
Chair-Side Traps Only	20,600	68%
Chair-Side Traps and Vacuum Filter Only	34,100	78%
Amalgam Separator	48,300	99.3%
Total	**103,000**	**--**

Sources: U.S. EPA, 2016; Vandeven and McGinnis, 2005.

11.1.3 National Estimate of Annual Non-Mercury Amalgam Metals in Dental Offices Wastewater

In addition to mercury, dental amalgam contains other metal constituents. EPA estimated pollutant loadings for four other metals contained in dental amalgam: silver, tin, copper, and zinc. The composition of amalgam is approximately 49 percent mercury, 35 percent silver, 9 percent tin, 6 percent copper, and 1 percent of zinc (Massachusetts Water Resources Authority, 2001). Using the mercury generation estimates in Chapter 11.1.1, EPA estimated the generation of metal waste in dental office wastewater (see Table 11-5).

Table 11-5. Calculation of Annual Untreated Non-Mercury Metal Generation from the Restoration and Removal of Dental Amalgam

<table>
<tr><th>Description</th><th>Pollutant in Dental Office Wastewater</th><th>Per Procedure</th><th>Annual Loading (Untreated)</th><th>Notes</th></tr>
<tr><td rowspan="2">Amalgam Restorations</td><td>Mercury</td><td>31 milligrams (mg)</td><td>2.4 tons (U.S.)</td><td rowspan="4">Estimate non-mercury metals entering wastewater based on ratio of amalgam composition: 49 percent mercury and 51 percent non-mercury metals.</td></tr>
<tr><td>Non-Mercury Metals</td><td>32 mg</td><td>2.5 tons (U.S.)</td></tr>
<tr><td rowspan="2">Amalgam Removals</td><td>Mercury</td><td>270 mg</td><td>34.8 tons (U.S.)</td></tr>
<tr><td>Non-Mercury Metals</td><td>281 mg</td><td>36.2 tons (U.S.)</td></tr>
</table>

Sources: U.S. EPA, 2016.

11.1.4 National Estimate of Annual Baseline Discharges of Non-Mercury Amalgam Metals from Dental Offices to POTWs

As with mercury pollutant loadings, EPA assumed chair-side traps and vacuum filters will result in 68 and 78 percent collection of all amalgam metals, respectively. EPA also assumed a 99.3 percent removal of all amalgam metals at offices with amalgam separators in place. Using the same methodology as described for mercury in Chapter 11.1.2 to calculate baseline pollutant loadings, EPA estimated the non-mercury metal mass loading generated by amalgam restorations as 2.5 tons per year. EPA similarly estimated the non-mercury metal mass loadings generated by amalgam removals as 36.2 tons per year. After accounting for existing technologies at dental offices, EPA calculated the current nationwide annual baseline loading of non-mercury metals discharged to POTWs from dental offices to be 5.3 tons, out of a total of 38.7 tons originally generated (U.S. EPA, 2016).

11.1.5 Total Annual Baseline Discharges to POTWs

After accounting for existing technologies at dental offices, EPA estimated dental offices collectively discharge 5.1 tons of mercury and 5.3 tons of additional metals to POTWs per year for a total discharge to POTWs of 10.4 tons annually.

11.2 National Estimate Of Annual Pollutant Reductions To POTWs Associated With The Final Dental Category Rule

EPA estimated that the approximately 54,700 dental offices without technology in place will install amalgam separators that meet the 2008 ISO 11143 standard with a median removal efficiency of 99.3 percent as a result of the final rule for the dental category. The combination of chair-side traps, vacuum filters and separators would then achieve 99.8 percent removal of total solids (i.e., all metals) from the dental wastewater (U.S. EPA, 2016). This would result in reduction of total mercury discharges to POTWs by 5.06 tons. Because dissolved mercury accounts for much less than 1 percent of total mercury (Stone, 2004), and because amalgam separators are not effective in removing dissolved mercury, EPA assumed the dissolved mercury contribution and associated reduction in loadings to be negligible.

Similarly, EPA estimated a reduction of non-mercury metal (i.e., silver, tin, copper, and zinc) discharges to POTWs of approximately 5.27 tons. Again, EPA assumes the dissolved metal content to be negligible.

Accordingly, the final rule would annually reduce mercury discharges by 5.06 tons and other metal discharges by 5.27 tons for a total annual reduction to POTWs of 10.33 tons.

11.3 National Estimate Of Annual Pollutant Reductions To Surface Waters Associated With The Final Dental Category Rule

In order to evaluate final discharges of mercury (and other metals) to waters of the United States by POTWs, EPA used its 50 POTW Study (U.S. EPA, 1982) to calculate POTW removals of each metal (see Chapter 5 for details). As explained above, at baseline and prior to implementation of the final rule, EPA estimated that, collectively, dental offices discharge 5.1

tons[43] of dental mercury annually to POTWs. Based on the 50 POTW Study, EPA estimates that POTWs remove 90.2 percent of the 5.1 tons of mercury from the wastewater. Thus, POTWs collectively discharge 1,003 pounds of dental mercury to surface waters annually.

Under the final dental category rule, over 98 percent of mercury solids currently discharged annually to POTWs will be removed prior to the POTW. The POTWs then further remove 90.2 percent of total mercury from the wastewater. This reduces the total amount of dental mercury discharged from POTWs nationwide to surface water to 11 pounds annually. In other words, discharges of mercury to waters of the United States from POTWs are expected to be reduced by 992 pounds per year[44] as a result of the final rule.

Based on the 50 POTW Study, POTWs remove the following from wastewater prior to discharge:

- 88 percent of total silver;
- 43 percent of total tin;
- 84 percent of total copper; and
- 79 percent of total zinc.

At baseline, EPA estimates that dental offices discharge 5.4 tons of non-mercury amalgam metals to POTWs annually. After treatment at the POTW, POTWs collectively discharge 2,178 pounds of non-mercury amalgam metals to surface waters annually. Following compliance with the final dental category rule, the non-mercury amalgam metal discharges from POTWs to surface waters will be approximately 24 pounds, a reduction of 2,153 pounds.[45] This results in the total reduction of amalgam metals (mercury and non-mercury) to waters of the United States by an estimated 3,146 pounds (U.S. EPA, 2016).

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[43] This may be a conservative assumption, particularly where sewers are designed for overflows (as is the case for combined sewers), or where sewers have overflows as a result of improper maintenance or accidents and natural disasters (e.g., floods or earthquakes).

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

[45] Numbers are rounded; therefore, subtraction of baseline and post-compliance pollutant removals may differ slightly from pollutant reduction value.

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Chapter 12
Cost-Effectiveness Analysis

EPA traditionally defines cost-effectiveness as the total incremental annualized cost of a pollution control option per total incremental toxic pound-equivalent (i.e., pound of pollutant adjusted for relative toxicity) removed by that control option. EPA uses the cost-effectiveness analysis primarily in comparing the removal efficiency of regulatory options under consideration for a rulemaking. A secondary use is to compare the cost-effectiveness of the final rule to those for effluent limitations guidelines and standards (ELGs) for other industries. This definition includes the concepts discussed in this chapter.

12.1 TOTAL INCREMENTAL ANNUALIZED COMPLIANCE COSTS

The cost-effectiveness analysis uses the estimated total annual costs of complying with the final rule. As described in Chapter 10.2.3, EPA developed two estimates of incremental costs, reflecting different distributions of numbers of chairs in dental offices. EPA adjusts the compliance costs to 1981 dollars to allow for comparison with cost-effectiveness values for other promulgated regulations for different industries. EPA adjusted the value using the Bureau of Economic Analysis GDP Implicit Price Deflators,[46] and calculates this adjustment factor as follows:

$$\text{Adjustment factor} = (1981\$) \div (2016\$) = \mathbf{48.52} \div \mathbf{110.39} = 0.440$$

Table 12-1 shows the estimated annualized compliance costs converted to 1981 dollars.

Table 12-1. Annualized Compliance Costs at Promulgation Year

Dental Office Distribution Data Source	Millions; 2016$	Conversion Factor	Millions; 1981$
ADA Colorado Survey	$53.5	0.44	$23.5
ADA National Survey	$54.8		$24.1

Source: U.S. EPA, 2016a

12.2 TOXIC WEIGHTING FACTORS

Because each pollutant differs in its potential harmful effects on human and aquatic life, EPA uses a toxic weighting factor (TWF) specific to each pollutant to calculate a toxicity-normalized pollutant removal value for use in the cost-effectiveness analysis.[47] The toxic

[46] EPA typically uses the Engineering News Record Construction Cost Index. However, this approach is not appropriate for this rule because the technology option does not require construction.

[47] See U.S. EPA, 2011 for details on toxic weighting factors.

weighting factor for each pollutant measures its toxicity relative to copper,[48] with more toxic pollutants having higher toxic weights. The use of toxic weights allows EPA to express the removals of different pollutants on a constant toxicity basis as toxic-weighted-pound-equivalents (lb-eq). In the case of indirect dischargers, the removal also accounts for the effectiveness of treatment at publicly owned treatment works (POTWs) and reflects the toxic-weighted-pound-equivalents after POTW treatment. Table 12-2 lists the TWFs for the pollutants found in dental discharges.

Table 12-2. Toxic Weighting Factors for Pollutants in Dental Amalgam

Pollutant	Toxic Weighting Factor
Total mercury	110
Silver	16.47
Tin	0.301
Copper	0.623
Zinc	0.047

Source: U.S. EPA, 2016b

12.3 Calculation Of Annual Total Incremental Pound-Equivalents Removed To Surface Waters

EPA estimated the annual reduction in pollutant loadings nationwide to waters of the United States associated with the final rule for each pollutant identified in dental amalgam.

Because this final rule is for indirect discharges, this estimate accounts for discharge reductions that occur at the publicly owned treatment works (POTW). See Chapter 11 of this document for further information on how loadings were calculated. EPA adjusts the reductions in a pollutant's discharges for an option, or pollutant removals, for toxicity by multiplying the estimated removal quantity for each pollutant by its TWF. EPA refers to these adjusted removals as toxic-weighted pound-equivalents (TWPEs). EPA summed the TWPE reductions for each pollutant to estimate the total annual incremental pound-equivalent reductions for the final rule. Table 12-3 presents the estimate of individual and total annual incremental pound-equivalent removals from surface waters for the final rule.

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

Table 12-3. Total Incremental Pound-Equivalents Removed from Surface Water Discharges[a]

Pollutant	Incremental Removals from Baseline (lbs/yr)	Toxic Weighting Factors	Incremental Removals from Baseline (lb-eq/yr)
Total mercury	992	110	109,146
Silver	848	16.47	13,961
Tin	1,067	0.301	321
Copper	196	0.623	122
Zinc	43.1	0.047	2.02
Total			123,552

Source: U.S. EPA, 2016a; U.S. EPA, 2016b

a – Numbers shown are rounded; multiplying values across the first two columns will not exactly equal the value in the last column

12.4 COST-EFFECTIVENESS RESULTS

Table 12-4 presents the cost-effectiveness data and results. The cost-effectiveness value for the final rule is $190 to $195 per lb-eq (1981$).

Table 12-4. PSES Cost-Effectiveness Analysis

Dental Office Distribution Data Source	Pre-Tax Total Annualized Costs (Millions; 1981$)	Removals (lbs-eq)	Average Cost-Effectiveness (1981$)
ADA Colorado Survey	$23.5	123,552	$190
ADA National Survey	$24.1	123,552	$195

Source: U.S. EPA, 2016a

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 a rule to the annual pounds-equivalent removed. Average cost-effectiveness can be thought of as the increment between no regulation and the rule. The technology basis for PSES in this final rule has a cost-effectiveness ratio of $190 to $195 per 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 found that PSES cost effectiveness ranges from approximately $1 per lb-equivalent (Inorganic Chemicals) to $380 per lb-equivalent (Transportation Equipment Cleaning) in 1981 dollars.

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Chapter 13
Environmental Impacts of Dental Mercury Discharges

Aside from mercury, other constituents of dental amalgam include the metals silver, tin, copper, zinc, indium, and palladium. Of the dental amalgam constituents, mercury is of greatest concern to human health because it is a persistent, bioaccumulative, toxic chemical and biomagnifies in aquatic food chains. For wastewater mercury discharges, the major route for human exposure to mercury discharged in wastewater is the consumption of mercury-contaminated fish.

13.1 Mercury In Dental Wastewater

Mercury discharged in dental wastewater is present in many forms, including elemental mercury bound to amalgam particulate, inorganic (ionic) mercury, elemental mercury, and organic mercury (methylmercury, or MeHg) (Stone et al., 2002). Table 13-1 presents the mean concentrations of mercury species measured in wastewater samples collected at the dental chair. Nearly all (>99.6 percent) of dental mercury discharges are in solid form (elemental mercury bound to amalgam particulate).

Table 13-1. Mean Concentrations of Mercury Species in Dental Wastewater

Mercury Form	Measured Concentration	Percent of Total Mercury
MeHg (methylmercury)	277.74 nanograms/liter (ppt)	0.0013%
Hg0 (unbound elemental mercury)	24.06 micrograms/liter (ppb)	0.112%
Hg+2 (ionic mercury)	54 micrograms/liter (ppb)	0.252%
Hg0 (elemental mercury bound to amalgam particulate)	21.360 milligrams/liter (ppm)	99.6%

Source: Stone, 2004.

While dissolved mercury (MeHg, unbound Hg0, Hg+2), makes up less than one percent of the total mercury in dental wastewater, there is increasing interest in the causes of dissolution and the extent to which dissolved mercury is present in dental wastewater. Dissolved mercury is a concern because elemental and ionic mercury can be converted to form additional methylmercury by bacteria, such as *Desulfobacteraceae* and *Desulfovibrionaceae,* which are present in wastewater (ACS, 2008). Methylmercury is particularly toxic to humans due to its ability to bioaccumulate in fish. When humans consume methylmercury, it targets the nervous system and can hinder a person's ability to walk, talk, see, and hear. Extreme cases of methylmercury poisoning can result in coma or death (WI DNR, 1997).

Researchers have detected concentrations of methylmercury in dental wastewater that are orders of magnitude higher than background methylmercury concentrations measured in environmental samples from open oceans, lakes, and rainfall. Concentrations of methylmercury in dental wastewater ranged from 0.90 to 26.77 milligrams per liter (mg/L). Such dissolved mercury concentrations can be high enough to violate local mercury discharge limits (Stone, 2004). In comparison, concentrations in environmental samples have ranged from 0.05 to 10.0

nanograms per liter (ng/L) (Stone et al., 2002). Researchers have concluded that sulfate-reducing bacteria are responsible for the presence of methylmercury in dental wastewater; however, it is not clear whether methylation occurs in the patient's mouth or in the discharge stream (ACS, 2008).

13.2 Dental Mercury Fate And Transport

The form of mercury discharged from dental practices is important to publicly owned treatment works (POTWs) because it can affect their ability to remove mercury from influent wastewater. Solid mercury particles will likely settle out of solution and adsorb to the wastewater treatment sludge. However, dissolved mercury can pass through treatment operations and enter surface waters. For the pass-through analysis conducted as part of this rulemaking (see Chapter 5.3), EPA used a 90 percent removal rate for total mercury.

POTWs manage their wastewater treatment sludge (biosolids) through beneficial reuse (60 percent) and via disposal (40 percent). Disposed biosolids are typically incinerated (22 percent of all biosolids) or disposed of in a landfill (18 percent of all biosolids) (U.S. EPA, 1999). Mercury is a relatively volatile metal that can be converted to a gas by incineration and emitted to the atmosphere. Once in the atmosphere, mercury is deposited into lakes and streams by rainfall. (WI DNR, 1997). In contrast, solid mercury particles disposed of in a landfill are unlikely to be released into the environment.

13.3 Environmental Assessment

EPA conducted a literature review concerning potential environmental impacts associated with mercury in dental amalgam discharged to surface water by POTWs (U.S. EPA, 2011). Studies indicate that dental offices are the largest source of mercury entering POTWs. The total annual baseline discharge of dental mercury to POTWs is approximately 10,239 pounds (5.1 tons): 10,198 pounds are in the form of solid particles (99.6 percent) and 41 pounds (0.4 percent) are dissolved in the wastewater (U.S. EPA, 2016). Through POTW treatment, approximately 90 percent of dental mercury is removed from the wastewater and transferred to sewage sludge. The 10 percent of dental mercury not removed by POTW treatment is discharged to surface water. EPA estimates that POTWs annually discharge approximately 1,003 pounds of dental mercury nationwide.

13.3.1 Mercury in Surface Water Discharges

Environmental assessment of impacts associated with POTW discharges of dental mercury is complicated by uncertainties about the fate and transport of mercury in aquatic environments. The elemental form of mercury used in dentistry has low water solubility and is not readily absorbed when ingested by humans, fish, or wildlife. However, elemental mercury may be converted into highly toxic methylmercury in aquatic environments by certain forms of anaerobic sulfate-reducing bacteria. Methylmercury 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 the 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 (Chin, et al., 2000).

The neurological effects of eating methylmercury-contaminated fish are well documented (WI DNR, 1997). Developmental effects to fetuses, infants, children, and fish consumption by women of childbearing age are of special concern. Neurological effects from predation of methylmercury contaminated fish have been documented to occur in wild populations of fish, birds, and mammals in many areas of the United States (WI DNR, 1997). A plausible link has been identified between anthropogenic sources of mercury (e.g., coal combustion) 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, or atmospheric deposition of mercury in the United States from sources in other countries. Given the current scientific understanding of the environmental fate and transport of mercury, it is not possible to quantify how much of the methylmercury in fish consumed by the U.S. population is contributed by U.S. emissions relative to international mercury sources or natural mercury sources.

EPA was unable to assess the 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.

13.3.2 Mercury in Biosolids

The Clean Water Act regulations known as *Standards for Use and Disposal of Sewage Sludge*, 40 CFR Part 503, control the land application, surface disposal, and incineration of sewage sludge generated by POTWs. Of the 11.2 billion dry pounds of sewage sludge generated annually, about 60 percent, or 6.7 billion pounds, are treated to produce biosolids for beneficial use as a soil amendment and applied to about 0.1 percent of agricultural lands in the United States (National Research Council, 2002). EPA estimates that approximately 5,500 pounds per year of dental mercury are contained in land-applied biosolids. Nevertheless, the mercury content of land applied biosolids has been documented to be well below the risk-based pollutant concentration limits set by 40 CFR 503.

Approximately 18 percent, or 2 billion pounds, of the sewage sludge generated annually by POTWs are surface disposed in sewage sludge mono-fills or municipal landfills (U.S. EPA, 1999). Approximately 1,700 pounds per year of dental mercury are contained in surface disposed sewage sludge. Pollutant discharge limits and monitoring requirements for surface disposed sewage sludge mono-fills are set by 40 CFR 503 and by 40 CFR 258 for municipal landfills. There may be additional state or local regulations that are more stringent than the federal biosolids regulations.

The remaining 22 percent, or 2.5 billion pounds, of sewage sludge generated annually by POTWs is disposed of through incineration (U.S. EPA, 1999). Incineration of sewage sludge emits an estimated 35 pounds of dental mercury to the atmosphere annually, of which approximately 11.5 pounds are deposited within the conterminous United States (U.S. EPA, 1997; U.S. EPA, 2005a; U.S. EPA, 2005b; and U.S. EPA, 2009). Approximately 2,000 pounds per year of dental mercury are contained in incinerated sewage sludge. 40 CFR 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 61.

13.3.3 Environmental Benefits of the Final Rule

While EPA did not perform an environmental benefits analysis of the final rule, due to insufficient data about the aquatic fate and transport of dental mercury discharged by POTWs, EPA was able to assess the qualitative environmental benefits based on existing information. For example, EPA identified studies that show that decreased point-source discharges of mercury to surface water result in lower methylmercury concentrations in fish. Moreover, several studies quantify economic benefits from improved human health and ecological conditions resulting from lower fish concentrations of methylmercury (U.S. EPA, 2011). The final pretreatment standards will produce human health and ecological benefits by reducing the estimated annual nationwide POTW discharge of dental mercury to surface waters from 1,003 pounds to 11 pounds (U.S. EPA, 2016). In addition, the decreased discharges to POTWs will result in a decrease of mercury in biosolids. EPA is unable to quantify the nationwide benefits of reducing the releases of mercury to air, landfills, air, surface water, and groundwater as a result of reduced mercury in biosolids that are subsequently incinerated, landfilled, and land applied.

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Chapter 14
Non-Water-Quality Environmental Impacts

The elimination or reduction of one form of pollution has the potential to aggravate other environmental problems, an effect frequently referred to as cross-media impacts. Sections 304(b) and 306 of the Clean Water Act (CWA) require EPA to consider non-water quality environmental impacts (NWQEIs), including energy impacts, associated with effluent limitations guidelines and standards (ELGs). To comply with these requirements, EPA considered the potential impact of the technology basis on energy consumption, air pollution, and solid waste generation.

As shown below, EPA anticipates that the rule would produce minimal non-water quality environmental impacts and as such determined they are acceptable. The chapters below summarize the NWQIs associated with the dental rule requirements.

14.1 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 standard. As described in Chapter 5, the wastewater treatment system at dental offices include the chair-side trap, vacuum pump with filter, and amalgam separator. Dental vacuum systems operate at a typical vacuum level of six to eight inches mercury and a typical airflow of seven standard cubic feet per minute per chair-side high volume inlet. Excess amalgam from new fillings, as well as amalgam from removed restorations, is rinsed into the chair-side drain. Amalgam separators typically 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. A few models do require a 110-volt outlet or come with a pump as part of their operation (McManus and Fan, 2003; USAF, 2011). Additionally, some separators have warning indicators that require a battery or power source. Neither of these pose any considerable energy requirements. As a result, EPA expects operation of an amalgam separator would pose negligible additional energy requirements on the existing vacuum pump.

Some units described in the literature may require small pumps to remove settled effluent from the separator (McManus and Fan, 2003). 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. Moreover, the addition of an amalgam separator is likely to reduce energy consumption at dental offices that do not currently employ an amalgam separator as it will prevent small particles from impeding the vacuum pump impeller. Just like a fan blade, a clean impeller is more efficient than a dirty impeller, and thus will draw less energy (Shelton & Bodman, 1995; Jacobsen & Chastain, 1994; Huyser, 2016). Based on this evaluation, EPA concluded there will be no significant non-water-quality environmental impacts associated with the energy requirements for the final rule.

14.2 SOLID WASTE GENERATION

In the absence of amalgam separators, a portion of the amalgam rinsed into chair-side drains is collected by chair-side traps and a portion of the amalgam suctioned into the vacuum line is collected by vacuum pump filters. The remainder is discharged to the publicly owned treatment works (POTW), where approximately 90 percent is removed from the wastewater and becomes part of the POTW sludge; the sludge may be land applied, disposed of in landfills or mono-fills, or incinerated. The final rule is expected to increase the use of amalgam separators nationwide—EPA expects almost 55,000 dental offices to install amalgam separators to comply with the final rule (see Table 10-2). Currently, just over 48,000 dental offices have separators installed (see Table 10-2). With the increased use of amalgam separators, there will be a corresponding increase in collection and recycling of used amalgam from spent canisters. EPA expects the operation and maintenance requirements associated with the amalgam separator compliance option included in the final rule will further promote recycling as the primary means of amalgam waste management, because many amalgam separator manufactures and dental office suppliers have begun offering waste handling services that send dental amalgam waste to resorting and recycling facilities. Nationally, EPA expects less dental amalgam will be discharged to POTWs leading to reductions in the amount of mercury discharged to surface waters and the amount of mercury currently land-applied, landfilled, or released to the air during incineration of sludge. Instead, EPA expects that the waste will be collected in separator canisters and recycled. After the amalgam containing waste has been recycled, the canisters are either recycled or landfilled. For purposes of assessing the incremental solid waste generation, EPA conservatively assumes all of the canisters are landfilled. EPA found that if each dental office generated an average of 2 pounds of spent canisters per year, the total mass of solid waste generated would still comprise less than 0.0001 percent of the 254 million tons of solid waste generated by Americans annually (U.S. EPA, 2013). Based on this evaluation of solid waste generation, EPA concluded that there will not be a significant incremental non-water-quality environmental impact associated with solid waste generation as a result of the final rule.

14.3 AIR EMISSIONS

While unbound mercury is highly volatile and can easily evaporate into the atmosphere, an estimated 99.6 percent of dental mercury discharges are in solid bound form (i.e., elemental mercury bound to amalgam particles) (Stone, 2004). Because nearly all dental mercury is bound to solid particles, it likely will not volatilize to the atmosphere. Other metals contained in mercury amalgams (silver, tin, copper, zinc, indium, and palladium) are much less volatile than mercury and are also in solid bound form and are also not likely to volatilize to the atmosphere. Therefore, EPA expects the final rule will not pose any increases in air pollution. In addition, because particulate mercury is removed prior to the generation of biosolids by POTWs, the portion of biosolids that is incinerated will produce less mercury in the air emissions. However, EPA is unable to quantify the reduction in air emissions as a result of less mercury in the biosolids that are incinerated. EPA concluded that there will be no significant non-water-quality environmental impacts associated with air emissions as a result of the final rule.

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Chapter 15
Implementation

This chapter provides guidance to dental dischargers and Control Authorities, such as publicly owned treatment works (POTWs) in implementing the final rule.

15.1 COMPLIANCE DEADLINE

For existing sources, the compliance date, meaning the date that existing sources subject to the rule must comply with the standards in this rule is three years after the effective date of the final rule. Specifying a compliance date of three years from the effective date of the final pretreatment standards rule is consistent with EPA's General Pretreatment Regulations, which require existing sources to meet categorical pretreatment standards within three years of the effective date of such standards, unless a shorter compliance time is specified therein. 40 CFR 403.6(b). After the effective date of the rule, new sources subject to this rule must comply immediately with the standards in this rule. EPA reasonably established that for purposes of this rule a new source is a dental discharger that first discharges to a POTW after the effective date of the final rule. New sources have the opportunity to incorporate into their facilities the best available demonstrated control technologies (unlike existing sources which have to retrofit) and Congress envisioned that new sources would do so prior to beginning to discharge.

Table 15-1 presents the implementation deadline for existing and new sources of dental dischargers.

Table 15-1. Compliance Deadline for Dental Offices Subject to the Final Rule

Dental Office	Requirement	Deadline
Existing Source	Comply with PSES	Three years after the effective date
New Source	Comply with PSNS	After the effective date of the rule, immediately

15.2 SUMMARY OF DENTAL OFFICE RESPONSIBILITIES

For dental offices that place or remove amalgam, the final rule requires installation, operation, and maintenance of one or more amalgam separators (or its equivalent) that are compliant with either the American National Standards Institute (ANSI) American National Standard/American Dental Association (ADA) Specification 108 for Amalgam Separators (2009) with Technical Addendum (2011) or the International Organization for Standardization (ISO) 11143 Standard (2008) or subsequent versions so long as that version requires amalgam separators to achieve at least a 95% removal efficiency. EPA does not expect *dental offices* to demonstrate a separator is compliant with one of these standards. Rather, as shown in Table 9-1, *manufacturers* obtain such demonstration for their amalgam separator models based on testing results from a qualified laboratory and make this information readily available. In addition, the ANSI and ISO standards require, among other things, marking of the amalgam separator (section 12 of the standard), and a test report (section 9 of the standard). Again, EPA expects the manufacturer of the amalgam removal device, and not the dental office, to maintain such testing reports and ensure the amalgam separator conforms to the marking requirements of the standard.

The final rule allows dental offices to continue to operate existing amalgam separators for their lifetime or ten years (whichever comes first), as long as the dental discharger complies with the other rule requirements including the specified BMPs, operation and maintenance, reporting, and recordkeeping requirements. Once the separator needs to be replaced or the ten-year period has ended, dental offices will need to replace the amalgam separator with one that meets the requirements of the final rule.

As an alternative to compliant amalgam separators, the rule provides that dental offices may also install, operate, and maintain one or more amalgam removal devices other than an amalgam separator (alternative device). Among other things, the rule requires that the alternative device be tested to demonstrate removal efficiency. In the case of alternative devices, the dental office must include information demonstrating that the alternative device meets the rule's design requirements in their One-Time Compliance Report. EPA expects manufacturers of alternative devices to provide such documentation to the dental office. Further details on the requirement of the final rule are included in Chapter 8.3.

The pretreatment standards also specify certain operating and maintenance requirements for the amalgam separator (or equivalent device). These include inspection in accordance with the manufacturer's operating manual to ensure proper operation and maintenance of the separator(s) and to confirm that all amalgam process wastewater is flowing through the amalgam retaining portion of the amalgam separator(s); replacement of the amalgam retaining unit in accordance with the manufacturer's operating manual or when the amalgam retaining unit has reached the maximum level, whichever comes; and repair or replacement of the separator as needed.

Solids collected by the amalgam separator may be a combination of dental amalgam, biological material from patients, and any other solid material sent down the vacuum line. The collected solids must be handled in accordance with federal, state and local requirements. To facilitate compliance with state and local requirements several amalgam separator manufacturers offer services that facilitate the transport of waste amalgam to facilities that separate mercury from other metals in dental amalgam and recycle the mercury, keeping it out of the environment. EPA recommends that dental dischargers take advantage of such services.

EPA is aware that some amalgam separator vendors (in addition to providing the needed equipment) or service providers offer service contracts to maintain the system. For example, the American Dental Association (ADA) established an affinity agreement with HealthFirst to offer ADA members discounted amalgam separators and waste management services (ADA Business Resources, 2014). These vendors also typically provide waste management services for the collected solids. Some vendors also provide the necessary documentation and reports required by existing state and local programs. EPA encourages but does not require dental offices to consider such services, as they may aid compliance with the rule.

Lastly, dental offices must follow to BMPs. They must not discharge waste amalgam (*e.g.,* dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices. They also must not clean dental unit water lines, chair-side traps, and vacuum lines that discharge amalgam process wastewater with oxidizing or acidic cleaners (*e.g.,* bleach, chlorine, iodine and peroxide) that have a pH lower than 6 or greater than 8.

Reporting Requirements

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

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

The One-Time Compliance Report must be signed by (1) a responsible corporate officer if the dental office is a corporation; (2) a general partner or proprietor if the dental office is a partnership or sole proprietorship; or (3) a duly authorized representative of the responsible corporate officer, or general partner or proprietor. This does not preclude a third party from submitting the report on behalf of a dental office as long as the submission also includes a proper signature as described above. As long as a dental office subject to the final is in operation, or until ownership is transferred, the dental office, or an agent or representative of the dental office, must maintain the One-Time Compliance Report required at § 441.50(a) and make it available for inspection in either physical or electronic form.

The final rule does not require electronic reporting nor does it prevent electronic reporting. Still, EPA recognizes that some Control Authorities may prefer to receive the one-time reports electronically or to provide affected dental dischargers with the option to report electronically. EPA also recognizes that electronic submittal of required reports could increase the usefulness of the reports, is in keeping with current trends in compliance reporting, and could result in less burden on the regulated community and the Control Authorities. EPA may develop and make available, via its E-Enterprise portal, an electronic reporting system that Control Authorities could use to facilitate the receipt of reports from dental dischargers, if they choose to do so.

Recordkeeping Requirements

The final rule requires dental offices, or an agent or representative of the dental office, to document certain operation and maintenance requirements and maintain all records of compliance, as described in the regulation, and to make them available for inspection. The final rule requires dental offices to document inspections, amalgam retaining unit replacement, that collected dental amalgam is handled appropriately (preferably recycled), and any repair or replacement of an amalgam separator or equivalent device. The dental office, or an agent or representative of the dental office, must maintain these records and make available for inspection in either physical or electronic form, for a minimum of three years. The dental office, or an agent or representative of the dental office, should also maintain either a physical or electronic copy of the manufacturer's operating manual for the current device.

15.3 CONTROL AUTHORITY OVERSIGHT/REPORTING

The final rule establishes for the purposes of Part 441, that dental dischargers are not significant industrial users (SIUs) or categorical industrial users (CIUs) as defined in 40 CFR 403 unless designated as such by the Control Authority. By establishing that dental dischargers are not SIUs or CIUs in the final rule, EPA eliminates the application of specific oversight and reporting requirements in 40 CFR 403 such as permitting and annual inspections of dental dischargers unless the Control Authority chooses to apply these requirements to dental offices. This means that Control Authorities have discretion under the final rule to determine the appropriate manner of oversight, compliance assistance, and enforcement.[49] Further, the final rule reduced reporting for dental offices (and associated oversight requirements by Control Authorities) in comparison to reporting requirements for other industries subject to categorical pretreatment standards, as it requires only a One-Time Compliance Report be submitted to the Control Authority. The One-Time Compliance Report requirements specific to dental dischargers are included in the final rule (40 CFR 441) rather than in the General Pretreatment Regulations so that they may be implemented directly. In summary, for the final rule, the Control Authorities must receive the One-Time Compliance Reports from dental dischargers and retain that notification according to the standard records retention protocol contained in 403.12(o).

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

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

Authorities, the ADA and other partners to tailor oversight and outreach to the issues where such oversight and outreach is most likely to achieve compliance across the dental sector.

15.4 VARIANCES

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

15.5 PHASE-OUT OF THE RULE

Dental dischargers that do not remove amalgam except in limited emergency and unplanned, unanticipated circumstances and that do not place dental amalgam can certify such in their One-Time Compliance Report submitted to the Control Authority. To clarify, the limited circumstances[50] provision applies to the removal, but not the placement of dental amalgam. A dental office that stocks amalgam capsules clearly intends to place amalgam, and does not represent the type of limited circumstances this provision is intended to address. Further, in EPA's view, dental offices that remove amalgam at a frequency more than five percent of its procedures are not likely engaging in limited, unplanned removals. EPA estimates that on average, a single chair dental office would remove amalgam 183 times per year (DCN DA00467). An amalgam removal rate that represents less than five percent of this frequency consists of approximately nine removals per year, on average, respectively. However, because EPA does not have, nor did commenters provide, data on the frequency of such unplanned and unanticipated instances nationwide, the final rule does not include a specific definition of limited circumstances. Rather, EPA expects a dental office to carefully consider its operation in light of the information provided above and only certify accordingly to their Control Authority if it meets the situation EPA described.

The final rule does not expire on a particular date. However, as use of dental amalgam as a treatment for dental cavities decreases, removals will eventually decrease as well, and dentists can ultimately certify that do not place amalgam and only remove dental amalgam in limited emergency or unplanned, unanticipated circumstances. This essentially creates an "off-ramp" for dental dischargers once dental amalgam placements and removals discontinue. A dental discharger that installs a separator and certifies its operation meets the requirements of the applicable performance standard in its One-Time Compliance Report that later changes it operation such that it no longer places dental amalgam, and does not remove amalgam except in

[50] As it has done here, EPA sometimes shortens "limited emergency and unplanned, unanticipated circumstances" to "limited circumstances." For purposes of this final rule, these terms are synonymous.

limited emergency and unplanned, unanticipated circumstances, may also elect to comply with this rule at that time via this provision. While the rule does not require such offices to submit a second One-Time Compliance Report, EPA recommends the office do so. At a minimum, EPA suggests the office prepare and sign a certification and retain it along with the original One-Time Compliance Report.

Also, section 307(b) requires EPA to revise its pretreatment standards for indirect dischargers ‘‘from time to time, as control technology, processes, operating methods, or other alternatives change.’’ See CWA section 307(b)(2). Section 304(g) requires EPA to annually review these pretreatment standards and revise them ‘‘if appropriate.’’ Although section 307(b) only requires EPA to revise existing pretreatment standards ‘‘from time to time,’’ section 304(g) requires an annual review. Therefore, EPA meets its 304(g) and 307(b) requirements by reviewing all industrial categories subject to existing categorical pretreatment standards on an annual basis to identify potential candidates for revision.

15.6 References

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Chapter 16
Quality Assurance Activities for the Dental Category Costing and Loading Analyses

The ELGs for the Dental Category are based on data generated or obtained in accordance with EPA's Quality Policy and Information Quality Guidelines. EPA's quality assurance (QA) and quality control (QC) activities for this rulemaking include developing, approving, and implementing Quality Assurance Project Plans for the use of environmental data generated or collected from sampling and analyses, existing databases, literature searches, and for developing any models that used environmental data.

For the costing and loading analyses, EPA only used secondary data (i.e., data not collected to specifically support the dental category rulemaking). EPA used secondary data to calculate compliance costs for dental offices to purchase and install treatment technologies (i.e., amalgam separators) to reduce mercury and other metal discharges to publicly owned treatment works (POTWs). EPA also used secondary data to calculate baseline and post-compliance pollutant loadings of mercury and other metals from dental offices to publicly owned treatment works (POTWs) and subsequently to waters of the United States.

EPA acknowledges that data provided in references include a certain level of uncertainty. To address this uncertainty, EPA completed sensitivity analyses for the compliance costs (see Chapter 16.4). Uncertainties may exist due to currency of the information (e.g., costs from a 2011 publication), limited number of data points (e.g., only two examples of installation costs for dental offices with 1 or 2 chairs), and other assumptions (e.g. use of average amalgam separator purchase, installation, replacement part, and recycling costs based on model dental offices).

This chapter presents the following:

- Cost drivers;
- Costs uncertainty;
- Loadings analyses uncertainties; and
- Alternative POTW mercury removal analysis.

16.1 Cost Drivers and Uncertainty with Compliance Costs

Costs may differ among dental offices. For example, amalgam separator costs may be less expensive for smaller sized dental offices (defined by the number of chairs) than for large dental offices or institutional facilities. Costs also vary by locality, dental office location, as well as each individual dental office's selected amalgam separator or other amalgam collecting device. Where available, EPA collected cost information that is based on dental office size (i.e., number of chairs) so that costs can be evaluated for a range of dental office sizes.

As detailed in Chapter 9, compliance costs for dental offices include one-time and annual costs. One-time costs include amalgam separator purchase cost, separator installation cost, and reporting costs (i.e., baseline compliance report). Annual costs include the following:

- Replacement of the amalgam-retaining unit (e.g., canister, cartridge, or filter);
- Amalgam separator inspection costs (assumed to incur monthly to represent rule requirement for inspection based on manufacturer's user manual);
- Separator maintenance/cleaning costs (assumed to incur biweekly to represent rule based on manufacturer's user manual);
- Oversight of amalgam separator repairs;
- Amalgam recycling preparation (assumed to incur twice per year to represent rule requirement based on manufacturer's user manual); and
- Annual amalgam recycling costs.

Factors that can influence the incremental compliance costs for a dental office include the number of amalgam placements and removals, volume of wastewater generated (e.g., use of wet or dry vacuum system), and number of chairs. EPA used model dental offices based on practice size and average costs for each model dental office to calculate the incremental compliance costs for dental offices to comply with the final rule (see Chapter 9). Actual costs to a specific dental office may be higher or lower depending on location, choice of control device, and office configuration.

As EPA compiled costing data, it found a wide range in amalgam separator design, including ease of use, technology used (e.g., filtration, sedimentation, ion exchange), efficiency, frequency and need for replacement parts, and types of services included in the cost (e.g., recycling). This resulted in a wide range of costs for purchasing amalgam separators and replacement part costs that exceeded the ±25 percent used for the quality assurance analysis.[51] Rather than arbitrarily selecting certain amalgam separators with similar costs (±25 percent), EPA captured a wide range of data points to estimate average incremental compliance costs for dental offices.

Amalgam separator purchase costs have a high variability due to a wide range in costs between different manufacturers, even after grouping costs by chair size. The largest range of amalgam separator costs were for dental offices with 3 to 5 chairs (approximately $325 to $1500). For the smallest dental office size (1 or 2 chairs), purchase costs ranged from $230 to $815. Amalgam separator costs for the 6-chair and 7 to 14-chair size groups were less variable (see Table 16-2). For large institutional offices (15 chairs), variability in costs ($1,510 to $4,510) may be partially due to the wide range in number of chairs at these facilities (i.e., can exceed 25 chairs). Because the amalgam separator costs increased with increasing size of the dental office, using the average provides a reasonable cost estimate.

Amalgam separator replacement part costs also have a high variability due to a wide range in costs between different manufacturers, even after grouping costs by chair size. In some cases, manufacturers recommend replacing the entire system which can be a higher cost than changing out a container or filter. The largest range of replacement part costs were for dental offices with 7 to 14 chairs (approximately $210 to $1500). For the smallest dental office size (1

[51] In the *Amalgam Separator Cost Spreadsheet* (U.S. EPA, 2016a), EPA compared each data point used in the analysis to the calculated average that EPA used to determine compliance costs for dental offices as a result of the final rule.

or 2 chairs), replacement part costs ranged from $160 to $650. Replacement part costs for the 3 to 5 chair and 6-chair size groups were closer in range, but costs could still be three times higher for one amalgam separator compared to another. Because the annual replacement part costs increased with increasing size of the dental office, using the average provides a reasonable cost estimate.

Installation costs also varied within each model dental office size group. This may be due to the location, layout, or plumbing configuration of the dental office. Because installation costs increased with increasing size of the dental office, using the average is reasonable even though there is variability in each model dental office size group (U.S. EPA, 2016b).[52]

16.2 DEVELOPMENT OF COST CALCULATION SPREADSHEETS

EPA developed several spreadsheets to estimate costs for dental offices to meet the Dental Category pretreatment standards, including requirements for BMPs, amalgam separators, maintenance of separators, and compliance reporting. EPA also developed a spreadsheet to estimate costs (burden) to Control Authorities that will receive baseline compliance reports and transfer of ownership forms from dental offices.

EPA revised the spreadsheet used at proposal to calculate amalgam separator costs (purchase cost, replacement parts cost, and recycling cost) by chair size. EPA performed the following steps to update the proposal costs:

1. Reviewed the amalgam separators used in the costing calculations to ensure they meet ISO 11143 (2008) / ANSI requirements. EPA removed those separators that do not meet the ISO standard (NH, 2015; USAF, 2011).[53] In addition, units no longer offered by manufacturers were also removed from the costing analysis[54] (Rebec Environmental, 2016; R&D Services, 2016; AB Dental Trends, 2016). EPA did not add any additional amalgam separators to the cost spreadsheet.

2. Revised costs based on 2016 data, either by identifying current online costs or converting costs to 2016 dollars. EPA converted costs to $2016 using RSMeans® Historical Cost Indexes, using the following equation:

$$\$2016 = \$Year \times \frac{Index_{2016}}{Index_{year}}$$

[52] In the *Amalgam Separator Installation Cost Spreadsheet* (U.S. EPA, 2016b), EPA compared each data point used in the analysis to the calculated average that EPA used to determine compliance costs for dental offices as a result of the final rule.

[53] New Hampshire's 2015 list of amalgam separators meeting the ISO 11143 standard for solids removal includes two units from Maximum Separation Systems (MSS 1000 and MS 2000) (NH, 2015). EPA did not find information on the MS 601 unit, and therefore, excluded it from the amalgam separator cost analysis.

[54] Proposal costs included six amalgam separators from Rebec Environmental. The website only lists three amalgam separator units (CATCH^{HG} 400, CATCH^{HG} 1000, and Custom Systems). Proposal costs included two 400 series units, two 1000 series units, and two 6000 series units (custom systems). For final costs, EPA combined the costing information to develop a range of purchase, replacement parts, and recycling prices to represent each series (i.e., 3 units total from Rebec Environmental).

3. For the calculation of annual replacement part costs, EPA assumed that the canister (or other container), filter, and cartridge replacements would occur no less frequently than annually. For annual replacement parts cost (minimum and maximum), there are five scenarios where calculations occur (i.e., not a direct transfer of cost from the referencex), listed below.

   i. If the manufacturer recommends exchanging the canister (or other container), filter, or cartridge more than every 12 months, EPA used the value replacement cost to represent the annual cost (i.e., assume the dental office will replace the part every year to comply with the dental category rulemaking). This value represents both the minimum and maximum cost for replacement parts each year for that amalgam separator.

   ii. If the manufacturer recommends exchanging the canister (or other container), filter, or cartridge less than every 12 months, EPA used the replacement cost to estimate the annualized cost to represent both the minimum and maximum annual cost. For example, if a manufacturer recommends replacing the filter every nine months, EPA calculated an annual cost using the following equation:

$$Annual\ Cost = Replacement\ Cost \times \frac{12\ months}{9\ months}$$

   iii. If the manufacturer lists a range of time when the canister (or other container), filter, or cartridge needs to be exchanged, EPA calculated a minimum and maximum annual cost, with the maximum no less than every 12 months. For example, a manufacturer recommends replacing the filter every 6 to 12 months, EPA calculated annual replacement parts costs using the following equations:

$$(Annual\ Cost)min = Replacement\ Cost \times \frac{12\ months}{12\ months}$$

$$(Annual\ Cost)max = Replacement\ Cost \times \frac{12\ months}{6\ months}$$

   iv. If the manufacturer recommends replacing the canister (or other container), filter, or cartridge every 6 to 18 months, the replacement costs would be the same as (c) listed above (i.e., 12-month maximum).

   v. For American Dental Accessories AD-1000 and Rasch AD-1500, filter changes occur every 18 months per dentist (MCES, 2009). These units are included in the 7+ chair size category, with a range of 7 to 12 chairs. EPA assumed there are 2 to 4 dentists working in a dental office with 7 to 12 chairs. This is based on the Safety Net Dental Clinic Manual recommendation of 3.0 operatories per dentist (National Maternal & Child Oral Health Resource Center, 2011).

The calculation of the replacement part costs would then be:

$$(Annual\ Cost)min = Replacement\ Cost \times \frac{12\ months}{18\ months} \times 2\ dentists$$

$$(Annual\ Cost)max = Replacement\ Cost \times \frac{12\ months}{18\ months} \times 4\ dentists$$

EPA revised the spreadsheet used at proposal to calculate incremental compliance the costs as calculated by chair size. The revisions included:

1. Removed the reporting burden estimate to complete a 90-day compliance form and annual compliance forms. Added a burden estimate (time) for dental offices to complete annual transfer of ownership forms. EPA assumed 10 percent of dental offices will submit a transfer of ownership form annually.

2. Revised number of dental offices by chair size used in the calculation sheet to reflect 2012 Economic Census numbers.

3. Revised installation costs included as inputs for the costing calculations based on comments received (used multiple study references).

4. Included cost offset for dental offices without technology in place based on a comment received on the proposed rule. See DCN DA00490 and DA00491.

5. Added the following annual (recurring costs): visual inspection recordkeeping, separator maintenance (e.g., replacement of amalgam retaining canister, cartridge or filter) recordkeeping, separator repair/recordkeeping, and recycling recordkeeping.

16.3 Activities for the Dental Category Loading Analysis

As described in Chapter 11, EPA calculated mercury and other metal loadings[55] from dental offices to POTWs and from POTWs to surface water on an industry-wide basis. Specific pollutant loadings from dental offices will vary based on the size of the dental practice, number of dental amalgam placements (or restorations) and removals performed at the office, and current treatment technology in place. EPA estimated baseline pollutant loadings and loading removals (or reductions) as a result of the final rule.

For baseline pollutant loadings, EPA accounted for current treatment technology in place at dental offices, including chair-side traps, vacuum system filters, and amalgam separators. For post-compliance pollutant removals, EPA assumed all dental offices would operate chair-side traps, vacuum filters, and amalgam separators with a median percent removal of 99.3 percent (U.S. EPA, 2016a; U.S. EPA, 2016c). To estimate discharges to surface water, EPA accounted for pollutant removal at the POTW by secondary treatment technologies.

EPA used different types of references for the loadings analysis including publications in a peer reviewed journal; government publications; industry, trade association, or vendor information; and other references (e.g. figure from a state website showing composition of dental

[55] Other metals include silver, tin, copper, and zinc.

amalgam). For each reference, EPA evaluated whether the data provided were current, complete, accurate, and reasonable. EPA also evaluated the uncertainty for each of the references.

Data from a publication in a peer reviewed journal are considered complete, accurate, and reasonable if the source is clearly written, documents any methodologies or assumptions, and where relevant, describes variability and uncertainty. The primary reference that EPA used for the loadings analysis is a 2005 publication from a peer reviewed journal: "An Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States" by Jay Vandeven and Steve McGinnis, published in *Water, Air, and Soil Pollution* (Vandeven & McGinnis, 2005). EPA reviewed the data source and confirmed that the publication presented the methodology, assumption, and data sources, was relevant to the dental industry, and where relevant, described the variability and uncertainty. The loadings analysis input data used from this reference include the following:

- 71,000,000 total restorations (placements) performed in the U.S. each year, as estimated by ADA in 1999. As noted in Vandeven and McGinnis, 2005, this number of total restorations correlated well with more recent estimates of mercury use in dentistry conducted by the U.S. Geological Society (USGS) in 2000. EPA received comments that the number of amalgam placements is declining in the U.S due to alternative filling materials and better dental health. Although EPA continued to use the number of total placements reported in this publication (71,000,000) for its loadings analysis, EPA conducted a sensitivity analysis to determine this factor's impact on the loadings analysis (see Chapter 16.5).

- 450 milligrams (mg) of mercury in amalgam capsules based on another peer reviewed journal.

- 340 mg of mercury used for an amalgam placement (75 percent of capsule). As reported in Vandeven and McGinnis, approximately 25 percent of the amalgam triturated by dentists is collected and recycled or disposed of as non-contact waste amalgam. The authors identified three references that placed the range between 15 and 50 percent and noted that the 25 percent is only an approximate value based on a government publication (Barron, T. 2001. *Mercury Headworks Analysis for 2000*. Palo Alto Regional Water Quality Control Plant).

- 9 percent of the mercury used for an amalgam placement (or 30.6 mg) enters the dental office wastewater. This estimate is based on a government publication (Barron, T. 2001. *Mercury Headworks Analysis for 2000*. Palo Alto Regional Water Quality Control Plant).

- 710 amalgam removals per year per general dentist. This estimate is based on normalized data from five municipal studies (i.e., government publications). EPA acknowledges that this estimate is based on older studies; however, EPA did not identify any more recent data to use in the loadings analysis. Because this is an uncertainty in the analysis, especially since the number of dentists between the proposed rule and final rule increased, EPA conducted a sensitivity analysis to determine this factor's impact on the loadings analysis (see Chapter 16.5).

- 440 amalgam removals per year per specialist. The authors did not have available data regarding the removal rate of amalgam at specialty offices. Therefore, the analysis assumes the rate of amalgam removal for specialists is similar to the rate of placements by specialists. As noted above, the number of removals per year at dental offices is an estimate with an elevated level of uncertainty and EPA performed a sensitivity analysis on this factor for the loadings calculation (see Chapter 16.5).

- 300 mg of mercury extracted from a patient's mouth during amalgam removal, which accounts for mercury loss during normal wear for the life of the filling. The estimate is based on two references, a publication in a peer reviewed journal and an industry study. The studies estimated 280 mg and 320 mg of mercury will be extracted at removal. The authors used the average mercury amount, resulting in a variability of ±7 percent.

- 90 percent of the amalgam filling removed mercury enters the dental office wastewater (270 mg). This estimate is based on a government publication (Barron, T. 2001. *Mercury Headworks Analysis for 2000*. Palo Alto Regional Water Quality Control Plant).

- Amalgam removal efficiency of chair-side traps of 68 percent, which is the average of two studies (both publications in peer review journals); one study determined a capture efficiency of 60 percent and the other, a capture efficiency of 75 percent. Therefore, the variability in the removal efficiency for chair-side traps can be as high as ±12 percent.[56] In addition, Vandeven and McGinnis note that the capture efficiency assumes that dentists properly maintain the chair-side traps.

- EPA used the estimated industry-wide amalgam removal efficiency of 78 percent to represent the capture efficiency of a chair-side trap and vacuum filter. The capture efficiency from properly maintained chair-side traps and vacuum filters was identified in the literature as 81 percent. Depending on the specific dental office and whether the technologies are properly maintained, there is a range of uncertainty in the amount of amalgam currently captured at these dental offices. EPA performed a sensitivity analysis on the treatment efficiency of chair-side traps and vacuum filters to determine the factors' impact on the loadings calculations (see Chapter 16.5).

- 20 percent of dental offices operate chair-side traps only. Vandeven and McGinnis reported that 80 percent of dental offices operate both chair-side traps and vacuum filters in their 2005 study. To determine the number of dental offices with treatment technology in place, EPA assumed 20 percent of offices operate chair-side traps only, and the remaining 80 percent of offices operate chair side traps and vacuum filters.[57]

EPA also used information from another publication from a peer reviewed journal, "The Effect of Amalgam Separators on Mercury Loading to Wastewater Treatment Plants" by M.E. Stone, published in the 2004 *Journal of the California Dental Association*, 32(7):593-600. As

[56] The range of capture efficiencies of chair-side traps has a variability of -12 percent to +10 percent.

[57] These dental offices may also use amalgam separators to control amalgam discharges.

discussed in the publication, mercury in wastewater from dental chairs contains primarily elemental mercury bound to amalgam particulate. Mercury is also present in the wastewater as ionic mercury (Hg^{+2}) and two forms of dissolved mercury, elemental mercury (Hg^{0}) and monomethyl mercury (MeHg). Six samples in the study present the concentration of each form of mercury in the dental wastewater. The portion of mercury bound to the amalgam particulate ranged from dissolved concentration ranges from 94.88 to 99.87 percent of the total mercury. For the loadings analysis, EPA assumed the amount of dissolved mercury in the wastewater is negligible. To determine the impact that the concentration of dissolved mercury can have on the pollutant loadings passing through the dental office control technologies, EPA conducted a sensitivity analysis (see Chapter 16.5).

Data from government publications are assumed to be complete, accurate, and reliable. The Vandeven and McGinnis, 2005 reference used data from government publications as described above. EPA also used government publications to determine the pollutant removal efficiencies at POTWs. In addition to the loadings analysis, EPA also used these values to determine whether the pollutants pass through POTWs (see Chapter 11). EPA confirmed that the data used are relevant to wastewater from the dental industry being treated at municipal treatment plants.

EPA also used trade association (ADA) data, *Supply of Dentists in the U.S. 2001 – 2015*, to determine the number of dentists and dental offices and type of practice (general or specialty). Using these data, EPA estimated the number of dentists and dental offices that may place or remove amalgam (U.S. EPA, 2016c). Although trade association data are less certain than peer-reviewed data, EPA determined that information from ADA are accurate and reliable. EPA evaluated the data for completeness and relevancy to the loadings analysis.

Other information obtained from non-industry, non-peer reviewed sources such as news sites and other websites are less certain than other sources, however, can be useful for general information or on a supplemental basis for the loadings analysis. EPA used a figure available on the Massachusetts Water Resources Authority website that shows the amalgam composition in typical dental fillings. After calculating mercury loadings, EPA used the percentages presented in the figure (49 percent mercury, 35 percent silver, 9 percent tin, 6 percent copper, and 1 percent zinc) to estimate non-mercury metal loadings. EPA evaluated data from this other source for relevancy when used in the loadings analysis.

EPA used multiple types of references to determine the amalgam capture efficiency of separators, including peer reviewed journal publications, government sources, industry sources, and communication with vendors. The capture efficiency for amalgam separators that meet the 2008 ISO 11143 / ANSI standard ranges between 95 and 99.96 percent. EPA used the median value of 99.3 percent. By definition of median, the actual removal efficiency at any given dental office will be higher in half of dental-offices, and lower in half of dental-offices. The median performance is based on lab studies conducted at extreme conditions: the testing is done at maximum water flow rates and under conditions of both empty and full. The performance of the separator when not operating under these extreme conditions is likely to be better.

EPA's loadings analysis evaluated nationwide discharges of mercury and other metals to POTWs. Loadings at individual dental offices and POTWs will vary by a number of factors, such as number of placements and removals and control technology currently in place. EPA acknowledges that data provided in references used for the loadings analysis include a certain level of variability and uncertainty. Variability and uncertainties may exist due to currency of the information (e.g., use of data from a 2005 publication), limited number of data points (e.g., amalgam separator efficiency based on certification test but may vary at a dental office), and other assumptions (e.g., amalgam removal efficiency for equipment – chair-side trap, vacuum filter, and amalgam separator are based on well-operated systems). The pollutant loadings that EPA presents in Chapter 11 and the corresponding cost effectiveness evaluation presented in Chapter 12 reflect the use of these data. Because the loadings to POTWs and surface water can vary based on a number of factors, EPA performed sensitivity analyses to determine how individual input data may affect the estimated baseline and post-compliance mercury loadings. EPA expects similar impacts apply to other metal loadings included in the analysis (silver, copper, tin, and zinc).

16.3.1 Development of Loadings Calculations

EPA developed several worksheets to estimate baseline and post compliance mercury and other metal loadings from dental offices. EPA used the most recent ADA data available on the number of dentists and dental offices (ADA, 2016). EPA also used the ADA data to revise the percent of specialty dental offices that may place or remove amalgam (see Chapter 10). Based on the revised amalgam separator models in the costing analysis, EPA calculated the median percent efficiency for amalgam separators that meet the 2008 ISO 11143 standard to be 99.3 percent (U.S. EPA, 2016a). EPA also revised the POTW percent removal for mercury to be three significant digits rather than two significant digits (90.2 percent rather than 90 percent).

16.4 SENSITIVITY ANALYSIS FOR COSTS

EPA used average costs for model dental offices to calculate one-time and annual compliance costs for dental offices that must comply with the dental category final rule. The incremental compliance costs that EPA presents in Chapter 9 and corresponding economic impacts presented in Chapter 10 reflect the use of these average model dental office costs. Table 16-1 provides component level costs based on the proposed rule cost components. Costs were calculated using both the Colorado Survey and the ADA survey, to show the costs are similar using both data sets. The contribution of the cost as a percent of the total cost is displayed below the cost.

Table 16-1. Dental Industry Cost Breakout by Component (Millions; 2016$)

Cost Category	Colorado Survey	ADA Survey
Equipment, installation, and year 10 replacement	$10.2 (16 percent)	$10.5 (16 percent)
O&M	$47.0 (72 percent)	$48.2 (72 percent)
Inspections by dental office, recordkeeping, reporting	$8.4 (13 percent)	$8.4 (13 percent)
Total	$65.5	$67.1

Because the costs to individual dental offices can vary, EPA performed sensitivity analyses to determine how individual cost elements may affect the estimated incremental compliance costs to dental offices for the final rule. This subsection includes a summary of the cost elements that can impact the incremental compliance costs due to their variability. EPA performed sensitivity analyses on the following cost elements: amalgam separator costs, annual replacement part costs, and annual maintenance costs.

16.4.1 Sensitivity Analysis for Amalgam Separator Purchase Costs

As a first step in conducting the sensitivity analysis, EPA compared the average amalgam separator purchase cost (used for final rule), least expensive retail price (lower-bound cost), and most expensive retail price (upper-bound cost) within each model dental office size (U.S. EPA, 2016a). As noted in, the largest range of amalgam separator purchase costs were for dental offices with 3 to 5 chairs. Table 16-2 presents the range of costs for individual amalgam separator models (lower and upper bound retail price) for each model dental office size group.

Table 16-2. Range of Amalgam Separator Purchase Costs ($2016) by Model Dental Office

Model Dental Office (Chair Size)	Number of Data Points	Amalgam Separator Purchase Cost ($2016)		
		Average[a]	Lower-Bound Retail Price (Percent Difference from Average)	Upper-Bound Retail Price (Percent Difference from Average)
1 or 2 Chairs	6	$437	$228 (-48%)	$813 (+86%)
3, 4, or 5 Chairs	5	$697	$325 (-53%)	$1,479 (+112%)
6 Chairs	3	$1,058	$895 (-15%)	$1,320 (+25%)
7 to 14 Chairs	10	$1,291	$731 (-43%)	$2,177 (+69%)
15 Chairs	6	$2,424	$1,512 (-38%)	$4,510 (+86%)

Source: U.S. EPA, 2016a; U.S. EPA, 2016e.
a – EPA used this purchase cost to calculate incremental compliance costs for dental offices.

For the 3,4, or 5-chair office size groups, the upper-bound amalgam separator costs are more than double the average cost (i.e., more than 100 percent). The 6-chair size group had the least variability in cost; this is most likely due to the small number of data points (three). As noted earlier, EPA did not want to arbitrarily select certain amalgam separators for its analysis solely due to similar costs. Instead, EPA captured a wide range of data points to represent the range of amalgam separators on the market. After calculating the average purchase price for each size category, EPA determined that the cost trend is reasonable (i.e., costs for dental offices with more chairs are greater than costs for dental offices with less chairs). EPA acknowledges that the purchase cost incurred by an individual dental office may be higher or lower than the average used in its analysis. On a nation-wide basis, EPA determined that the use of the average purchase price provided a reasonable estimation of the costs incurred by dental offices. Because EPA expects dentists will select an appropriate separator model for their particular office, and because EPA has identified at least 26 amalgam separators that could be used by dentists to meet rule requirements, the use of average costs most likely overstates the average costs per dentist of the rule.

EPA commonly evaluates one-time (or capital) costs on an annualized basis to determine the economic achievability of regulatory options. EPA compared the annualized costs for the range of amalgam separator purchase costs within each model dental office size group. EPA annualized costs across a 10-year basis[58] for the average amalgam separator purchase cost, lower-bound retail price, and upper-bound retail price for each model dental office size group. Table 16-3 presents the costs annualized across 10-years.

Table 16-3. Annualized Amalgam Separator Purchase Costs ($2016) by Model Dental Office

Model Dental Office (Chair Size)	10-Year Annualized Amalgam Separator Purchase Cost ($2016)		
	Average	Lower-Bound Retail Price	Upper-Bound Retail Price
1 or 2 Chairs	$44	$23	$81
3, 4, or 5 Chairs	$70	$33	$148
6 Chairs	$106	$90	$132
7 to 14 Chairs	$129	$73	$218
15 Chairs	$242	$151	$451

Source: U.S. EPA, 2016e.

Looking at the conservative, upper-bound estimate of amalgam separator purchase costs, the final rule would cost dental offices between $81 and $451 per year, depending on the size of the dental office. As noted earlier, some dental offices may purchase amalgam separators that cost more or less than the average purchase cost used in the economic analysis for the final rule. EPA found that the annualized cost to purchase an amalgam separator accounting for the upper-bound of the purchase price range is affordable.

The capital costs are annualized over 10 years, assuming a 7 percent discount rate these costs, thus approximately 13.9 percent of the capital cost is incurred per year. Thus a 10 percent increase in capital costs would result in less than a two percent increase in annual costs. As presented above, equipment and installation costs are 16 percent of the total costs to dentists. A two percent increase in annual costs results in no significant change in total costs. EPA concludes that capital costs and installation is not a driver of total rule costs.

16.4.2 Sensitivity Analysis for Amalgam Separator Replacement Part Costs

EPA calculated annual costs for model dental offices to replace the amalgam-retaining unit of the amalgam separator using two factors 1) retail price of the replacement part (in 2016 dollars) and 2) manufacturer's recommended replacement frequency. The recommend replacement frequency can be a range (e.g., 6 to 8 months) or specific time (e.g., every 12 months.). For each amalgam separator, EPA calculated a minimum and maximum annual cost based on the frequency of replacing the part. EPA assumed a maximum frequency of 12 months for replacing the amalgam-retaining unit (U.S. EPA, 2016a). Replacement parts include filters, cartridges, canisters, and collection containers. For a few models, the amalgam-retaining unit is reusable and therefore, the minimum annual cost for replacement parts is $0. Dental offices using

[58] EPA assumed a 10-year life for amalgam separators in its economic analysis (see Chapter 10).

separators with reusable containers would only incur costs to recycle or dispose of the retained amalgam. In addition, some models require the replacement of the entire amalgam separator.

EPA compared the range of annual amalgam separator replacement part costs, accounting for retail price and frequency of replacement, within each model dental office size (U.S. EPA, 2016a). Table 16-4 presents the average replacement part costs (used for final rule), lowest annual replacement part cost (lower-bound cost), and highest annual replacement part cost (upper bound cost) for each model dental office size group.

Table 16-4. Range of Annual Replacement Part Costs ($2016) by Model Dental Office

Model Dental Office (Chair Size)	Number of Data Points	Annual Replacement Part Cost ($2016)		
		Average[a]	Lower-Bound Annual Cost (Percent Difference from Average)	Upper-Bound Annual Cost (Percent Difference from Average)
1 or 2 Chairs	6	$275	$0 (-100%)[b]	$648 (+135%)
3, 4, or 5 Chairs	5	$386	$223 (-42%)	$699 (+81%)
6 Chairs	3	$559	$0 (-100%)[b]	$1,083 (+94%)[c]
7 to 14 Chairs	10	$732	$0 (-100%)[b]	$1,522 (+108%)
15 Chairs	6	$1,078	$518 (-52%)	$1,679 (+56%)

Source: U.S. EPA, 2016a; U.S. EPA, 2016e.
a – EPA used this annual cost to calculate incremental compliance costs for dental offices.
b – One amalgam separator in this model dental office size category offers reusable replacement parts (i.e., annual costs equal $0).
c – Upper-bound annual cost based on replacing entire amalgam separator.

The upper-bound annual replacement costs are more than double the average costs for two model dental office size groups: 1 to 2 chairs (+135 percent) and 7 to 14 chairs (+108 percent). This range in annual costs does indicate some variability in the annual costs that may be incurred by dental offices to comply with the final rule. As with the purchase costs, EPA did not want to arbitrarily select certain amalgam separators for its costing analysis solely due to similar costs. Instead, EPA captured a wide range of data points for the range of amalgam separators on the market. EPA used the average annual cost by model dental office as a best representation of the replacement parts costs for dental offices nationwide. After calculating the average annual replacement part costs for each size category, EPA determined that the cost trend is reasonable (i.e., annual costs for dental offices with more chairs are greater than annual costs for dental offices with less chairs). EPA acknowledges that the annual replacement part cost incurred by an individual dental office may be higher or lower than the average used in its analysis.

EPA determined the impact that the range of replacement part costs has on the total annual costs incurred by dental offices. Table 16-5 presents the total annual costs for dental offices based on the average replacement part cost, lower-bound replacement part cost, and upper-bound replacement part cost for each model dental office size group. The table includes the following:

- Average: total annual cost for dental offices to comply with the final rule using the average replacement part costs presented in Table 16-4. For example, the total annual costs for the 1 or 2 chair size group includes the $275 replacement part cost plus visual inspection costs, amalgam recycling costs, etc.

- Lower-bound: total annual cost for dental offices to comply with the final rule using the lower-bound replacement part costs presented in Table 16-4. For example, the total annual costs for the 1 or 2 chair size group includes the $0 replacement part cost plus visual inspection costs, amalgam recycling costs, etc.

- Upper-bound: total annual cost for dental offices to comply with the final rule using the upper-bound replacement part costs presented in Table 16-4. For example, the total annual costs for the 1 or 2 chair size group includes the $648 replacement part cost plus visual inspection costs, amalgam recycling costs, etc.

Table 16-5 also presents the percent difference in the total annual costs for dental offices based on the range of replacement part costs.

Table 16-5. Total Annual Incremental Compliance Costs Based on the Range of Replacement Part Costs by Model Dental Office

Model Dental Office (Chair Size)	Annual Incremental Compliance Costs ($2016)		
	Average Used for Final Rule	Based on Lower-Bound Replacement Part Cost (Percent Difference from Average)	Based on Upper-Bound Replacement Part Cost (Percent Difference from Average)
1 or 2 Chairs	$486	$211 (-57%)[a]	$859 (+77%)
3, 4, or 5 Chairs	$597	$434 (-27%)	$910 (+52%)
6 Chairs	$770	$211 (-73%)[a]	$1,294 (+68%)[b]
7 to 14 Chairs	$943	$211 (-78%)[a]	$1,733 (+84%)
15 Chairs	$1,289	$729 (-43%)	$1,890 (+47%)

Source: U.S. EPA, 2016e.
a – One amalgam separator in this model dental office size category offers reusable replacement parts (i.e., annual costs equal $0).
b – Upper-bound annual cost based on replacing entire amalgam separator.

Looking at the conservative, upper-bound estimate of replacement part costs, the final rule would cost dental offices between $859 and $1,890 per year, depending on the size of the dental office. EPA found that dental offices have a wide selection of amalgam separator models and associated costs. Using the upper-bound estimate of total annual costs, EPA determined that the final rule is affordable (see the economic analysis in the economic analysis 10).

16.4.3 Sensitivity Analysis for Amalgam Separator Maintenance Costs

The cost for maintaining the amalgam separator at a dental office is based on a number of factors: 1) frequency of maintenance; 2) time needed to complete maintenance activities; and 3) labor rate. For the costing analysis, EPA assumed maintenance would be performed by a dental assistant every two weeks and that each maintenance session would take 15 minutes (on average). Maintenance activities may include visual checks of the system (e.g., check fill line) or replacing the canister, filter, or cartridge as recommended by the manufacturer. As part of the literature review, EPA found that the changing of the replacement parts (e.g., canister, filter, or cartridge) may occur as frequently once per week to once per year (U.S. EPA, 2008). The frequency of maintenance depends on manufacturer's recommendation and the number of dental amalgam placements and removals performed by the dental office. The assumption of biweekly maintenance for the amalgam separator is highly conservative in view of the range of maintenance recommendations of the separator manufacturers (see Chapter 6). This comprises one of the larger cost elements for smaller office sizes (1-2 chairs or 3-5 chairs).

EPA compared the range of annual costs incurred by model dental offices using various frequency of maintenance activities – i.e., annually (lower-bound cost) to weekly (upper-bound cost) (U.S. EPA, 2016e). The annual costs include labor costs to perform the maintenance activity and labor costs to maintain the records (assumed to be 5 minutes per activity). Table 16-6 presents the range of annual maintenance costs for all model dental office sizes based on varying frequency of maintenance.

Table 16-6. Range of Annual Maintenance Costs ($2016) Based on Frequency of Maintenance

Frequency of Maintenance	Annual Maintenance Cost ($2016)		
	Maintenance Activity	Recordkeeping	Total [b]
Weekly	$231	$77	$308
Biweekly[a]	$115	$38	$154
Monthly	$53	$18	$71
Biannually	$9	$3	$12
Annually	$4	$1	$6

Source: U.S. EPA, 2016a; U.S. EPA, 2016e.
a – EPA used this annual cost to calculate incremental compliance costs for dental offices.
b – Total annual cost may not equal summation of maintenance and recordkeeping costs due to rounding.

Based on manufacturer recommendations for amalgam separator replacement parts, EPA found that filters, cartridges, canisters, and collection containers are mostly likely replaced at a frequency of every six to 12 months. Annual maintenance costs would then be over ninety percent lower than the estimate included in the annual incremental compliance costs for the final rule. However, as a conservative estimate, EPA assumed biweekly maintenance.

EPA determined the impact that the range of maintenance costs (based on varying frequency) has on the total annual costs incurred by dental offices. Table 16-7 presents the annual costs for dental offices based on biweekly maintenance (used for final rule), annual maintenance (lower-bound cost), and weekly maintenance (upper-bound cost) for each model dental office size group.

Table 16-7. Total Annual Incremental Compliance Costs Based on the Range of Maintenance Frequency by Model Dental Office

Model Dental Office (Chair Size)	Annual Incremental Compliance Costs ($2016)		
	Costs for Final Rule, Biweekly Maintenance	Lower-Bound Cost, Annual Maintenance (Percent Difference)	Upper-Bound Cost, Weekly Maintenance (Percent Difference)
1 or 2 Chairs	$486	$338 (-30%)[a]	$640 (+32%)
3, 4, or 5 Chairs	$597	$449 (-25%)	$751 (+26%)
6 Chairs	$770	$622 (-19%)[a]	$924 (+20%)[b]
7 to 14 Chairs	$943	$795 (-16%)[a]	$1,097 (+16%)
15 Chairs	$1,289	$1,141 (-11%)	$1,443 (+12%)

Source: U.S. EPA, 2016e.

For all model dental office size groups, the annual incremental compliance costs using the lower-bound maintenance cost and upper-bound maintenance cost are within 32 percent of the annual incremental compliance costs used to evaluate the final rule. Based on the range of maintenance frequencies, the final rule would cost smaller dental offices between $338 and $640 per year (1 or 2 chairs) and $449 an $751 per year (3,4, or 5 chairs).

The O&M costs are 72 percent of the total costs and therefore comprise a cost driver in this analysis. As noted above, EPA assumed biweekly maintenance of all amalgam separators even though this is one of the most frequent maintenance intervals identified in the amalgam separators evaluated. EPA found that the annual compliance costs, even accounting for biweekly maintenance, are affordable (see the economic analysis in Chapter 10).

16.5 SENSITIVITY ANALYSIS FOR LOADINGS

EPA completed sensitivity analyses for the loadings calculations to evaluate the impact of certain input data on baseline and post-compliance mercury loadings. EPA evaluated the following input data: number of amalgam placements, number of amalgam removals, removal efficiency of chair-side traps and vacuum filters, and quantity of dissolved mercury in dental office wastewater. EPA also conducted a sensitivity analysis on the removal of mercury at POTWs.

16.5.1 Sensitivity Analysis for Number of Amalgam Placements Performed Annually by Dental Offices

The input data with the most impact on the calculated pollutant loadings are the number of placements and removals of dental amalgam nationwide. In EPA's loadings analysis, placements accounted for 6.5 percent of all mercury entering dental office wastewater annually. The use of dental amalgam is declining due to a number of factors such as alternative filling types (e.g., composites) and improved dental health. For the loadings analysis, EPA used input data from a 2005 study that reported ADA's estimated number of placements in 1999 (71 million). In 2009, the Food and Drug Administration (FDA) estimated that the use of dental amalgam for fillings in 2016 will only be 41 million, a decrease of 42 percent (74 FR 38685). Similarly, the number of removals will likely decrease over time (albeit with a delay) based on less use of dental amalgam as a filling material.

EPA conducted a sensitivity analysis on the loadings calculations to determine the impact that the number of dental amalgam placements (or restorations) has on the loadings analysis. EPA compared the amount of mercury entering dental office wastewaters annually using two different number of annual placements: 71 million amalgam fillings (quantity used as input to the analysis) and 41 million amalgam fillings. EPA calculated the mercury in dental office wastewaters from amalgam placements to be 2.4 tons per year and 1.4 tons per year, respectively. The total mercury in the wastewater at dental offices (i.e., accounting for placements and removals) decreased by 3 percent, from 37.2 tons per year to 36.2 tons per year, when the quantity of amalgam filling placements decreased by 42 percent (U.S. EPA, 2016c; U.S. EPA, 2016d).

EPA determined the impact that the reduced number of placements has on the total mercury discharged to POTWs (accounting for removal technology at the dental office) and from POTWs to surface waters. Table 16-8 presents the results of the comparison.

Table 16-8. Impact of Dental Amalgam Placements on Annual Mercury Loadings

Number of Amalgam Placements [a]	Total Annual Mercury Loadings		
	Discharged to POTW (lbs/yr)	Discharge to Surface Waters (lbs/yr)	Percent Difference Total Discharge
Baseline Pollutant Loadings			
71 million [b]	10,200	1,003	NA
41 million	9,960	976	-3%
Post-Compliance Pollutant Reductions			
71 million [b]	10,100	992	NA
41 million	9,850	965	-3%
Post-Compliance Pollutant Loadings			
71 million [b]	115	11.2	NA
41 million	111	10.9	-3%

Source: U.S. EPA, 2016c; U.S. EPA, 2016d.
Acronyms: lbs/yr (pounds per year); NA (not applicable).
a – EPA used 71 million amalgam placements as input to the loadings analysis for the final rule based on a 2005 study. In 2009, the FDA estimated that the use of dental amalgam for fillings in 2016 will only be 41 million. EPA determined the impact that the number of dental amalgam placements has on the annual mercury loadings.
b – Number of amalgam placements used in the loadings analysis for the final rule.

Based on 41 million placements per year, the total annual loading of mercury to POTWs is 9,960 pounds per year (lbs/yr) (4.98 tons per year), a decrease of 3 percent compared to the loadings analysis (71 million placements). The total annual loading of mercury to surface waters is 111 lbs/yr (41 million placements), compared to the loadings analysis estimate of 115 lbs/yr. Although this analysis shows that the mercury loadings in EPA's analysis may be slightly higher assuming larger number of placements, the alternate data only changes the total loadings by -3 percent.

Another set of data (in comments from NACWA) suggested 52 million restorations per year. The FDA data for 41 million is a lower value than the 52 million, and the total loadings changed by less than 3 percent, therefore EPA simply notes the alternative data from NACWA would change total loadings by approximately 2 percent.

16.5.2 Sensitivity Analysis for Number of Amalgam Removals Performed Annually by Dental Offices

In EPA's loadings analysis, removals accounted for 94 percent of all mercury entering dental office wastewater. The rate of dental amalgam removals is based on studies prior to 2005; however, EPA did not identify any more recent estimates. For the loadings analysis, EPA assumed 710 amalgam removals each year per general dentist and 440 amalgam removals each year per specialty dentist. Based on the number of dentists by type of practice (ADA, 2016), EPA estimated that dental offices performed 117 million amalgam removals each year. While some data suggests fewer placements and restorations are occurring, the dental amalgam already in place in people's mouths would still need to be removed, and this would occur over a period of several decades. Even if EPA were to assume a one-third reduction in removals, and thus a one-third reduction in loads, the discharge of several tons of mercury per year to POTWs is significant. This scenario would not change the POTW pass-through analysis. Because one-third fewer removals occur under this scenario, and approximately one-third fewer dentists would incur the costs of amalgam separators, thus there would be no change in EPA's cost effectiveness. The final rule requires dental offices to collect mercury waste at the point of generation, rather than allowing mercury to continue to POTWs where it may be discharged to surface waters or become part of the POTW biosolids, whose management may result in diffuse releases of the mercury into the environment (see Chapter 13).

16.5.3 Sensitivity Analysis on the Efficiency of Chair-Side Traps and Vacuum Filters

EPA used treatment capture efficiencies for well-operated chair-side traps and vacuum filters to estimate mercury loadings. An estimated 20 percent of dental offices operate only chair-side traps (i.e., no vacuum filter) (Vandeven & McGinnis, 2005). EPA used an amalgam removal efficiency of 68 percent for chair-side traps; however, the range of efficiencies reported is 60 to 75 percent. Therefore, the mercury and metal loadings currently discharged may be higher or lower at a particular dental office. EPA did not have data on the range of removal efficiencies for chair-side traps and vacuum filters (combined), therefore the variability associated with the capture efficiency used for the loadings analysis (78 percent)[59] is not known. However, EPA acknowledges that actual removals at individual dental offices will vary.

EPA estimated the mercury loadings for the range of chair-side trap only capture efficiencies. Next, EPA estimated mercury loadings for the range of chair-side trap and vacuum filter (combined) capture efficiencies. EPA selected a range of 68 to 81 percent; the 68 percent is the capture efficiency used for chair-side traps only in the loadings analysis and 81 percent is the efficiency (prior to weighted-average calculations) reported in Vandeven and McGinnis, 2005. Table 16-9 and Table 16-10 present the results baseline and post-compliance mercury loadings for each range of capture efficiencies.

[59] EPA's data source for the capture efficiency for chair-side traps and vacuum filters is Vandeven and McGinnis, 2005. The 78 percent capture efficiency is the weighted-average amalgam removal efficiencies at dental offices (those using chair-side traps only and those using both chair-side traps and vacuum filters).

Table 16-9. Impact of Chair-Side Trap Capture Efficiencies on Annual Mercury Loadings

Chair-Side Trap Capture Efficiency	Total Annual Mercury Loadings		
	Discharged to POTW (lbs/yr)	Discharge to Surface Waters (lbs/yr)	Percent Difference Total Discharge
Baseline Pollutant Loadings			
60 percent	11,400	1,120	+12%
68 percent [a]	10,200	1,003	NA
75 percent	9,200	901	-10%
Post-Compliance Pollutant Reductions			
60 percent	11,300	1,109	+12%
68 percent [a]	10,100	992	NA
75 percent	9,080	890	-10%
Post-Compliance Pollutant Loadings [b]			
60 percent	115	11.2	0%
68 percent [a]	115	11.2	NA
75 percent	115	11.2	0%

Source: U.S. EPA, 2016c; U.S. EPA, 2016d.
Acronyms: lbs/yr (pounds per year); NA (not applicable).
a – Chair-side trap capture efficiency used in the loadings analysis for the final rule.
b –For the post-compliance pollutant loadings, EPA assumed that all dental offices will install amalgam separators and use a filter on their vacuum system. The post-compliance loadings calculations are based on the removal efficiency of the chair-side trap and vacuum filter (combined) and the amalgam separator.

Table 16-10. Impact of Chair-Side Trap and Vacuum Filter (Combined) Capture Efficiencies on Annual Mercury Loadings

Chair-Side Trap Capture Efficiency	Total Annual Mercury Loadings		
	Discharged to POTW (lbs/yr)	Discharge to Surface Waters (lbs/yr)	Percent Difference Total Discharge
Baseline Pollutant Loadings			
68 percent	12,700	1,247	+24%
78 percent [a]	10,200	1,003	NA
81 percent	9,490	930	-7%
Post-Compliance Pollutant Reductions			
68 percent	12,600	1,231	+24%
78 percent [a]	10,100	992	NA
81 percent	9,390	921	-7%
Post-Compliance Pollutant Loadings			
68 percent	167	16.3	+46%
78 percent [a]	115	11.2	NA
81 percent	99.0	9.70	-14%

Source: U.S. EPA, 2016c; U.S. EPA, 2016d.
Acronyms: lbs/yr (pounds per year); NA (not applicable).
a – Capture efficiency of chair-side trap and vacuum filter used in the loadings analysis for the final rule.

The capture efficiency of chair-side traps impacts the baseline pollutant loadings and post-compliance pollutant reductions; however, the efficiency has no impact on the post-compliance loadings. To calculate the post-compliance pollutant loadings, EPA assumed that all dental offices will install amalgam separators. In order to operate the amalgam separator, the dental office must have a vacuum system and EPA assumed a filter would be part of the post-compliance treatment technology. The post-compliance loadings calculations are based on the removal efficiency of the chair-side trap and vacuum filter (combined) and the amalgam separator.

The analysis shows that the pollutant loadings from dental offices are impacted by the capture efficiency of these control devices, along with the capture efficiency of the amalgam separators. However, EPA found that the range in pollutant loadings is reasonable. In all cases, the final rule will result in more than 9,000 pounds of mercury being removed from discharges to POTWs each year.

16.5.4 Sensitivity Analysis for Dissolved Mercury Concentration in the Wastewater

To simply for the pollutant loadings analysis, EPA assumed the dissolved mercury in the dental office wastewater was negligible. Therefore, EPA applied control technology removal efficiencies to the estimated total mercury entering wastewater at the dental office and discharging to the POTW. Based on sample data included in Stone, 2004, EPA found this assumption to be reasonable. The study reported that between 94.88 to 99.87 percent of total mercury in dental office wastewater was bound to the amalgam particle. The remaining percent of the total mercury was comprised of elemental mercury, ionic mercury, and monomethyl mercury.

Dissolved mercury is not controlled by chair-side traps, vacuum filters, or amalgam separators. Therefore, dissolved mercury in dental office wastewater will not be captured by the control technology and will discharge to the POTW. To determine the impact that the concentration of dissolved mercury has on the pollutant loadings passing through the dental office control technologies, EPA used the percent of mercury bound to amalgam particles to estimate potential range of dissolved mercury in the wastewater (0.13 to 5.12 percent).

EPA estimated that dental offices generate 37.2 tons per year of mercury in the wastewater. Assuming 0.13 to 5.12 percent mercury becomes dissolved in the wastewater, the dissolved mercury loadings passing through control technologies at the dental office ranges from 0.048 to 1.90 tons per year. This would result in 5.16 to 6.76 tons of total mercury discharging to the POTW (after accounting for baseline treatment of particulate mercury). In the loadings analysis for the final rule, EPA estimated 5.12 tons per year of mercury discharges to POTWs (0 percent dissolved mercury in the wastewater). Based on this sensitivity analysis, the dissolved mercury could increase the **total** mercury discharged to POTWs by one to 32 percent (U.S. EPA, 2016d).

16.6 NACWA DATA

In determining whether pollutants pass through a POTW when considering the establishment of categorical pretreatment standards, EPA compares the median percentage of the pollutant removed by POTWs achieving secondary treatment with the median percentage of the pollutant removed by facilities meeting BAT effluent limitations. EPA deems a pollutant to pass through a POTW when the percentage removed by POTWs is less than the percentage removed by direct dischargers complying with BPT/BAT effluent limitations. Historically, EPA's primary source of POTW removal data is its 1982 "Fate of Priority Pollutants in Publicly Owned Treatment Works" (also known as the 50 POTW Study). This well documented study presents data on the performance of 50 POTWs achieving secondary treatment in removing toxic pollutants.

In response to the proposed rule, the National Association of Clean Water Agencies (NACWA) cited a voluntary study of its member POTWs, and suggested their study data would better represent POTW mercury removals today than the 50 POTW Study. In fully considering these data, EPA analyzed the voluntary survey including data from 41 POTWs and found that numerous data would not satisfy the data editing criteria applied to the 50 POTW Study. The NACWA data included data points representing combined data rather than raw data, order of magnitude outlier concentrations, and incorrectly reported units of measure. Other discrepancies between data and analyses from the 50 POTW Study and NACWA survey calculations include upward bias of using data from voluntary respondents, representing non-detect influent concentrations as zero rather than the actual reported value, inclusion of several POTWs using BNR (biological nutrient removal) and other advanced treatment expected to perform better than secondary, overrepresentation of areas with existing dental amalgam reduction programs, and underrepresentation of certain geographical areas. Sensitivity analyses around these data are found in the record (U.S. EPA, 2016b).

EPA has determined these data are not representative of POTWs with secondary treatment, and has concluded the 50 POTW Study data are the best data for assessing POTW mercury removals. Therefore, EPA is not using these alternative data for assessing POTW pass through. However, EPA found that even if EPA were to accept these data, the median POTW mercury removal as presented in these alternative data under the most data inclusive scenario (e.g. not applying the full data editing criteria EPA applied to the 50 POTW Study data) is 94 percent. This median mercury removal is not comparable to the 50 POTW study as stated above. Nevertheless, if the results of this sensitivity analysis were used to evaluate POTW pass through as described in Chapter 5, EPA concludes there is pass through.

16.7 References

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Chapter 17
Glossary and List of Acronyms

ADA – American Dental Association.

AMSA – Association of Metropolitan Sewerage Agencies.

Amalgam – dental filling that is formed using liquid mercury and a metal powder mixture, often supplied in capsules. Amalgam fillings contain approximately 49 percent mercury and a mixture of metals—silver, tin, copper, and sometimes zinc, indium, or palladium – in the powder mixture.

Amalgam Separator – treatment technology used at dental offices to remove solid particulates from the wastewater.

BAT – The best available technology economically achievable, as described in Sec. 304(b)(2) of the Clean Water Act.

BMP – Best management practice. The Clean Water Act authorize EPA to prescribe BMPs as part of effluent limitations guidelines and standards, or as part of a permit.

BPT – The best practicable control technology currently available, as described in Sec. 304(b)(1) of the Clean Water Act.

Categorical Pretreatment Standards – Limitations on pollutant discharges to POTWs promulgated by EPA in accordance with Section 307 of the Clean Water Act that apply to specified process wastewaters of particular industrial categories.

CFR – Code of Federal Regulations, published by the U.S. Government Printing Office. A codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the federal government.

CIU – Categorical Industrial User. An industrial user subject to national categorical pretreatment standards.

Control Authority – POTW, state, or EPA Region that is responsible for permitting, sampling, and inspecting industrial users that discharge to the POTW. The Control Authority is (1) the POTW if the POTW's submission for its pretreatment program (§403.3(t)(1)) has been approved in accordance with the requirements of §403.11; or (2) the Approval Authority (state or EPA Region) if the submission has not been approved.

CWA – Clean Water Act. Federal legislation enacted by Congress to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Federal Water Pollution Control Act of 1972, as amended, 33 U.S.C. 1251 et seq.).

DCN – Document Control Number.

Direct Discharge – The discharge of a pollutant or pollutants directly to a water of the United States.

Discharge – The conveyance of wastewater to: (1) United States surface waters such as rivers, lakes, and oceans, or (2) a publicly owned, privately owned, federally owned, combined, or other treatment works.

DMR – Discharge Monitoring Report.

Effluent Limitation – Any restriction, including schedules of compliance, established by a state or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents that are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean. (CWA Sections 301(b) and 304(b).)

ETV – Environmental Technologies Verification.

EPA – U.S. Environmental Protection Agency.

FDA – Food and Drug Administration.

FFDCA – Federal Food, Drug, and Cosmetic Act.

Filtration – A process for removing particulate matter from water by passage through porous media.

FR – Federal Register, published by the U.S. Government Printing Office, Washington, D.C. A publication making available to the public regulations and legal notices issued by federal agencies.

Indirect Discharge – The discharge of a pollutant or pollutants to a POTW.

Ion exchange – Process using a resin formulated to adsorb cationic or anionic species.

ISO – International Organization for Standardization.

IU – Industrial User.

Loadings – Mass of pollutants being discharged in the wastewater from dental offices to POTWs and from POTWs to surface waters.

Mercury – As it pertains to the dental industry, mercury is a component of amalgam fillings. As found in wastewater, mercury is a concern to human health because it is a persistent, bioaccumulative, toxic element; certain microorganisms can change mercury into methylmercury, a highly toxic form that builds up in fish, shellfish, and animals that eat fish.

Mono-fill – An ultimate disposal technique for wastewater treatment plant sludge in which the sludge is applied to a landfill designed for sludge only.

MOU – Memorandum of Understanding.

NACWA – National Association of Clean Water Agencies.

NAICS – North American Industry Classification System. This system is a unique method for classifying business establishments. Adopted in 1997 to replace the old Standard Industrial Classification (SIC) system, it is the industry classification system used by the statistical agencies of the United States.

NPDES – The National Pollutant Discharge Elimination System, authorized under Sec. 402 of the Clean Water Act. NPDES requires permits for discharge of pollutants from any point source into waters of the United States.

NSPS – New source performance standards, as described in Sec. 306 of the CWA.

OSHA – Occupational Safety and Health Administration.

POTW – Publicly owned treatment works, as defined at 40 CFR 403.3(o). POTWs are generally any state or municipality-owned sewage treatment plant that recycles, reclaims, or treats liquid municipal sewage and/or liquid industrial wastes.

PPA – Pollution Prevention Act of 1990 (42 U.S.C. 13101 et seq., Pub.L. 101-508, November 5, 1990).

Pretreatment –The reduction of the amount of pollutants, the elimination of pollutants, or the alteration of the nature of pollutant properties in wastewater prior to or in lieu of discharging or otherwise introducing such pollutants into a POTW.

Pretreatment Standard – A regulation that establishes industrial wastewater effluent quality required for transfer to a POTW (CWA Section 307(b)).

PSES – Pretreatment standards for existing sources, as described in Sec. 307(b) of the CWA.

PSNS – Pretreatment standards for new sources, as described in Sec. 307(b) and (c) of the CWA.

QSC – Quicksilver Caucus of the Environmental Council of States.

RCRA – Resource Conservation and Recovery Act (PL 94-580) of 1976, as amended (42 U.S.C. 6901, et seq.).

SBA – Small Business Administration.

Sedimentation – Separation of solids and liquids from mixtures (solid settling).

SIC – Standard Industrial Classification. A numerical categorization system used by the U.S. Department of Commerce to catalogue business entities and economic activity. SIC codes refer to the products, or groups of products, produced or distributed, or to services rendered, by an operating establishment. SIC codes are used to group establishments by the goods and services they provide and the economic activities in which they are engaged. SIC codes often denote a facility's primary, secondary, tertiary, etc. economic activities.

SIU – Significant Industrial User. An indirect discharger that is the focus of control efforts under the national pretreatment program. This includes all indirect dischargers subject to national categorical pretreatment standards, and all other indirect dischargers that contribute 25,000 gallons per day or more of process wastewater, or which make up five percent or more of the hydraulic or organic loading to the POTW, subject to certain exceptions.

Sludge – The accumulated solids separated from liquids during processing (treatment).

Surface Waters – Waters of the United States including, but not limited to, oceans and all interstate and intrastate lakes, rivers, streams, creeks, mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, and natural ponds.

TCLP – Toxicity Characteristic Leaching Procedure. See 40 CFR 261.24.

TRI – Toxics Release Inventory.

TWF – Toxic Weighting Factor. A factor developed for various pollutants using a combination of toxicity data on human health and aquatic life. EPA uses toxic weighting factors in determining the amount of toxicity that a pollutant may exert on human health and aquatic life relative to other pollutants.

TWPE – Toxic Weighted Pound-Equivalent. Pound of pollutant adjusted for relative toxicity; determined by multiplying the pound of pollutant by the TWF.

VSQG – Very Small Quantity Generators.

Wastewater – For this document, water emanating from dental office.