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# Technical and Economic Development Document for the Proposed Effluent Limitation Guidelines and Standards for the Dental Category

United States
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# Technical and Economic Development Document for the Proposed Effluent Limitation Guidelines and Standards for the Dental Category (40 CFR 441)

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# SECTION 1
# BACKGROUND

This section provides background information on the development of effluent limitation guidelines and standards proposed for the Dental Category. Sections 1.1 and 1.2 present the legal authority and discuss the regulatory background for the proposed rule, respectively. Section 1.3 provides a history of activities related to Dental Category rulemaking.

## 1.1 LEGAL AUTHORITY

The U.S. Environmental Protection Agency (EPA) is proposing effluent limitation guidelines and standards (ELGs) for the Dental Category (40 CFR 441) under the authority 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 also authorizes EPA to establish national technology-based effluent limitation guidelines and standards (effluent guidelines or ELGs) for discharges from different categories of point sources, such as industrial, commercial, and public sources.

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

Direct dischargers must comply with effluent limitations in NPDES permits. Indirect dischargers (who discharge through POTWs) must comply with pretreatment standards.

Technology-based effluent limitations in NPDES permits are derived from effluent limitation guidelines (CWA sec. 301 and 304) and new source performance standards (sec. 306) promulgated by EPA, or are based on best professional judgment in cases where EPA has not promulgated an applicable effluent guideline or new source performance standard. Additional limitations based on water quality standards (sec. 301(b)(1)(C) and 303) may also be included in the permit in certain circumstances. The ELGs are established by regulation for various categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

EPA promulgates national effluent limitation guidelines and standards of performance for major industrial categories for three classes of pollutants: (1) conventional pollutants (total suspended solids, oil and grease, biochemical oxygen demand, fecal coliform, and pH); (2) toxic pollutants (e.g., toxic metals such as chromium, lead, mercury, nickel, and zinc; toxic organic pollutants such as benzene, benzo-a-pyrene, phenol, and naphthalene) as specified in sec. 307 of the Act; and (3) non-conventional pollutants, which are neither conventional nor toxic (e.g., ammonia-N, formaldehyde, and phosphorus).

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

1. <u>Best Available Technology Economically Achievable (BAT)</u>

   BAT effluent limitation guidelines apply to direct dischargers of toxic and nonconventional pollutants. In general, BAT effluent limitation guidelines represent the best economically achievable performance of facilities in the industrial subcategory or category. The factors considered in assessing BAT include the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the process employed, potential process changes, and non-water-quality environmental impacts including energy requirements, and such other factors as the Administrator deems appropriate. The Agency has considerable discretion in assigning the weight to be accorded these factors. An additional statutory factor considered in setting BAT is economic achievability. Generally, EPA determines economic achievability on the basis of total costs to the industry and the effect of compliance with BAT limitations on overall industry and subcategory financial conditions. Where existing performance is uniformly inadequate, BAT may reflect a higher level of performance than is currently being achieved based on technology transferred from a different subcategory or category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

2. <u>New Source Performance Standards (NSPS)</u>

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

3. Pretreatment Standards for Existing Sources (PSES)

   Pretreatment standards apply to discharges of pollutants to POTWs rather than discharges to waters of the United States. Pretreatment Standards for Existing Sources (PSES) are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs, including sludge disposal methods of POTWs. Categorical pretreatment standards for existing sources are technology-based and are analogous to BAT effluent limitation guidelines.

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

4. Pretreatment Standards for New Sources (PSNS)

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

5. 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), holding that EPA's use of non-numerical effluent limitations in the form of Best Management Practices are effluent limitations under the CWA; and Natural Res. Def. Council, Inc. v. EPA, 673 F.2d 400, 403 (D.C. Cir. 1982) which states "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 Pollution Prevention Act

The Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101 et seq., Public Law 101-508, November 5, 1990) "declares it to be the national policy of the United States that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or release into the environment should be employed only as a last resort..." (Sec. 6602; 42 U.S.C. 13101 (b)). In short, preventing pollution before it is created is preferable to trying to manage, treat, or dispose of it after it is created. The PPA directs the Agency to, among other things, "review regulations of the Agency prior and subsequent to their proposal to determine their effect on source reduction" (Sec. 6604; 42 U.S.C. 13103(b)(2)). EPA reviewed this effluent guideline for incorporation of pollution prevention measures.

According to the PPA, source reduction reduces the generation and release of hazardous substances, pollutants, wastes, contaminants, or residuals at the source, usually within a process. The term source reduction "include[s] equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training or inventory control. The term ‘source reduction' does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to or necessary for the production of a product or the providing of a service" (42 U.S.C. 13102(5)). In effect, source reduction means reducing the amount of a pollutant that enters a waste stream or that is otherwise released into the environment prior to out-of-process recycling, treatment, or disposal.

### 1.2.3 The National Pretreatment Program, 40 CFR 403

The General Pretreatment Regulations of 40 CFR 403 establish responsibilities among federal, state, and local government; industry; and the public to implement pretreatment standards to control pollutants that pass through or interfere with the POTW treatment processes or that can contaminate sewage sludge. The regulations, which have been revised numerous times since originally published in 1978, consist of 20 sections and seven appendices. The General Pretreatment Regulations use two terms describing oversight responsibilities under those regulations. One is the term Control Authority. The “Control Authority” refers to the POTW if the POTW has an approved pretreatment program, or the Approval Authority if the program has not been approved. The term Approval Authority describes the party with responsibility to administer the National Pretreatment Program which is either a state with an approved state pretreatment program or, in a state without an approved pretreatment program, the EPA region for that state [40 CFR § 403.3(f)]. An approved pretreatment program comprises legal authorities, procedures, funding, local limits, enforcement response plan, and the list of significant industrial users, all of which the Control Authority uses to implement the General Pretreatment Regulations.

The General Pretreatment Regulations apply to all nondomestic sources that introduce pollutants into a POTW. These sources of indirect discharges are also commonly referred to as Industrial Users or IUs. All IUs are subject to general pretreatment standards (40 CFR 403), including a prohibition on discharges causing "pass through" or "interference" (i.e., cause the POTW to violate its permits limits, or interfere with the operation of the POTW or the beneficial use of its sewage sludge). All POTWs with approved pretreatment programs must develop local limits to implement the general pretreatment standards. All other POTWs must develop such local limits where they have experienced "pass through" or "interference" and such a violation is likely to recur. There are approximately 1,500 POTWs with approved pretreatment programs and 13,500 small POTWs that are not required to develop and implement pretreatment programs.

## 1.3 REGULATORY HISTORY OF THE DENTAL CATEGORY

This section presents a brief history of activities related to Dental Category rulemaking. Section 1.3.1 discusses EPA's Detailed Study of the Dental Category. Section 1.3.2 discusses the 2008 memorandum of understanding (MOU) to reduce mercury discharges. Section 1.3.3 describes the American Dental Association's Best Management Practices and support of a national rulemaking. Section 1.3.4 describes existing state and local programs for dental discharges.

### 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 State and Local Programs

Currently, 12 states (Connecticut, Louisiana, Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Oregon, Rhode Island, Vermont, and Washington) have implemented mandatory programs to reduce dental mercury discharges.[1] Additionally, at least 19 localities similarly have mandatory dental reduction pretreatment programs. These mandatory programs require the use of amalgam separators and Best Management Practices. Removal efficiency requirements for separators in mandatory program jurisdictions vary from 95 percent to 99 percent. See Sections 6.2 and 6.3 of this document for more details on these programs.

## 1.4 REFERENCES

ADA. 2007. Best Management Practices for Amalgam Waste. Updated July 2007. Document Control Number (DCN) DA00165.

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

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

# SECTION 2
# SUMMARY AND SCOPE

Across the United States, many states and POTWs (also referred to as municipal wastewater treatment plants) are working to reduce discharges of mercury to POTWs. Numerous 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). Amalgam dental fillings contain mercury and other metals. Mercury discharges can result when dentists dispose of old amalgam fillings from patients' cavities, and dispose of excess amalgam after placing a new filling.[2] A study funded by the American Dental Association (ADA) published in 2005 estimated that dental offices contributed more than 50 percent (6.5 tons of 12.3 tons) of mercury entering POTWs (Vandeven and McGinnis, 2005).[3]

Mercury is a persistent and bioaccumulative pollutant with well-documented effects on human health. On November 6, 2013, the United States joined the Minamata Convention on Mercury, a new multilateral environmental agreement (not yet in force) that addresses specific human activities that are contributing to widespread mercury pollution. The agreement identifies dental amalgam as a mercury-added product regarding which certain measures should be taken. Specifically, the Convention lists nine measures for phasing down the use of mercury in dental amalgam, including promoting best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land. Nations that are parties to the Minamata Convention will be required to implement at least two of the nine measures addressing dental amalgam.

EPA estimates that 4.4 tons of mercury from waste dental amalgam are discharged into POTWs (U.S. EPA, 2011a). The physical processes at POTWs remove approximately 90 percent of the mercury in wastewater. This mercury transfers to the biosolids (or sewage sludge) generated during primary and secondary treatment processes (U.S. EPA, 1982). Mercury from amalgam can enter the environment through the incineration, landfilling, and land application of sludge, or through surface water discharge from POTWs. Once deposited, certain microorganisms can change mercury into methylmercury, a highly toxic form that builds up in fish, shellfish, and animals that eat fish. Fish and shellfish are the main sources of methylmercury exposure to humans.

The proposed regulations for the dental industry include pretreatment standards for the control of mercury in wastewater. This section summarizes the proposed rule, its application, and subcategorization.

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

[3] EPA performs a similar calculation to estimate current mercury discharges from dental facilities. See Section 11 of this document.

## 2.1 SUMMARY OF THE PROPOSED RULE

EPA is proposing technology-based pretreatment standards under the Clean Water Act (CWA) for discharges of pollutants into POTWs from existing and new dental offices[4] that discharge dental amalgam. The proposed rule would require dental offices to control the discharge of mercury and other metals in dental amalgam into POTWs based on the best available technology or best available demonstrated control technology (amalgam separators) and the use of best management practices (BMPs). The BMPs are (1) eliminating the flushing of scrap amalgam down drains and (2) cleaning chair-side traps with non-bleach, non-chlorine cleaners. EPA is also proposing to amend selected parts of the General Pretreatment Regulations (40 CFR 403) to streamline oversight requirements for the Dental Category.

EPA expects that compliance with this proposed rule would reduce the transfer of metals to POTWs by 8.8 tons per year, almost half of which (4.3 tons) is mercury (U.S. EPA, 2011a). EPA estimates the annual cost of the proposed rule would be $44 to $49 million (U.S. EPA, 2011b). EPA developed the proposed rule based on proper operation and maintenance of amalgam separators that remove at least 99.0 percent of total mercury from amalgam process wastewater, along with the use of the two BMPs.

Affected dental offices could meet the standard by using, properly operating, and maintaining a dental amalgam separator certified to achieve at least 99.0 percent reduction of total mercury according to the 2008 ISO 11143 standard (ISO, 2008), performing certain BMPs, and certifying to this effect. Affected dental offices could also meet the standard by certifying that they do not install or remove amalgam. ADA recommends that its dentists use the technology on which the rule is based (i.e., amalgam separators and BMPs) (ADA, 2007; ADA, 2010). Further, 12 states have implemented mandatory dental mercury discharge reduction programs that require amalgam separators and BMPs. For dental offices that have not yet installed amalgam separators, EPA estimates that this is a low-cost technology with an approximate average annual cost of $700 per office (U.S. EPA, 2011b). Opportunistic removal of concentrated sources of mercury through low-cost amalgam separators at dental offices is a common sense solution to managing mercury at the point in the waste stream where it is most concentrated, and from where the mercury would otherwise be released to air, land, and water.

EPA is also proposing to amend selected parts of the General Pretreatment Regulations (40 CFR 403) in order to streamline permitting and oversight requirements specific to the dental sector. When categorical pretreatment standards apply to an industry, certain oversight requirements are created. As defined in 40 CFR 403, facilities that are subject to categorical pretreatment standards are referred to as Categorical Industrial Users (CIUs). The number of dental offices that would likely be subject to national pretreatment standards is approximately ten times the current number of CIUs. The proposed changes to 40 CFR 403 reflect EPA's recognition that the current regulatory framework needs to be adjusted for the effective implementation and enforcement of these pretreatment requirements on the dental industry. Therefore, EPA is proposing a new classification of CIU, specifically tailored to the proposed rule: Dental Industrial User (DIU). EPA is proposing that DIUs not be subject to the oversight

[4] This document uses the general term "offices" to refer to any dentistry practice or facility that places or removes dental amalgam containing mercury.

requirements for Significant Industrial Users (i.e., control mechanism issuance requirement, annual inspection, and sampling requirements). Rather, EPA is proposing to allow Control Authorities to focus their oversight efforts on dental offices that fail to meet the compliance requirements of the DIU.

## 2.2 APPLICABILITY OF THE PROPOSED RULE

EPA has not identified dental offices discharging amalgam waste directly to waters of the United States. Because EPA has very limited information on any direct discharge of dental amalgam, EPA is not proposing effluent limitation guidelines and new source performance standards for direct dischargers at this time.

The proposed pretreatment standards apply to wastewater discharges to POTWs from offices where dentistry is performed, including institutions, permanent or temporary offices, clinics, mobile units, home offices, and facilities, including dental facilities owned and operated by federal, state, or local governments. EPA is not proposing to include wastewater discharges from dental offices specializing exclusively in 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 Section 4.2, these specialty practices do not place (restore) or remove dental amalgam, and thus EPA does not expect these offices to have any discharges of dental amalgam.

## 2.3 SUBCATEGORIZATION

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

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

## 2.4 References


ADA. 2007. Best Management Practices for Amalgam Waste. Updated July 2007. Document Control Number (DCN) DA00165.

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

ISO. 2008. International Organization for Standardization. ISO 11143:2008 Dentistry - Amalgam Separators Standard. July. DCN DA00138.

Larry Walker Associates. 2002. Mercury Source Control and Pollution Prevention Program Evaluation. Prepared for Association for Metropolitan Sewerage Agencies. AMSA. March (Updated July). DCN DA00006.

U.S. EPA. 1982. *Fate of Priority Pollutants in Publicly Owned Treatment Works*. EPA-440-1-82-303. September. DCN DA00244.

U.S. EPA. 2011a. EPA Analysis: Part 441 Option Cost Calculations. MS Excel™ file. Office of Water. Washington, DC. DCN DA00146.

U.S. EPA. 2011b. Economic Analysis for the Dental Amalgam Rule. MS Excel™ file. Office of Water. Washington, DC. DCN DA00145.

Vandeven, J., and S. McGinnis. 2005. An Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States. Water, Air and Soil Pollution. 164:349-366. DCN DA00163.

# SECTION 3
# DATA COLLECTION ACTIVITIES

EPA collected data from a variety of sources for the proposed Dental Amalgam Rule, 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 section includes a description of each data source; Section 4 through Section 14 of this document includes 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. EPA also conducted a POTW pass-through analysis on mercury for the industry. 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 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.

## 3.3 MEETINGS WITH STAKEHOLDERS

EPA participated in several meetings with stakeholders including the Environmental Council of the States, environmental organizations, the American Dental Association (ADA), and the National Association of Clean Water Agencies (NACWA). Sections 3.3.1 through 3.3.4 summarize information collected during these meetings.

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

### 3.3.2 Environmental Organizations

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

### 3.3.3 American Dental Association (ADA)

EPA met with ADA in 2010 and 2011. ADA submitted data to EPA on their recently adopted principles for addressing mercury discharges from dental offices, the number of specialty offices in the industry, the geographic distribution of dental offices, financial characteristics of the industry, and operating characteristics of the industry (ADA, 2010).

### 3.3.4 National Association of Clean Water Agencies (NACWA)

EPA met with NACWA in 2010 and 2011 to discuss the impact of pretreatment standards on POTWs. NACWA provided EPA information on its members' experiences with handling mercury wastes from dental offices, implementing pretreatment programs for dental offices, and implementing pretreatment standards for industries with similar characteristics as the dental industry. 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 (U.S. EPA, 2011).

## 3.4 AMALGAM SEPARATOR MANUFACTURERS (VENDOR CONTACTS)

EPA met with, or participated in calls with, representatives of multiple amalgam separator manufacturers (ERG, 2010; ERG and Air Techniques, 2011; ERG and American Dental Accessories, 2011; ERG and DRNA, 2011; ERG and Rebec Solutions, 2011; ERG and SolmeteX, 2011). 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.

## 3.5 AIR FORCE STUDY

In anticipation of the proposed Dental Amalgam Rule, 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 ISO 11143 certified, 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.

## 3.6 REFERENCES

ADA. 2010. ADA Principles to be Used to Develop Mandatory Separator Pretreatment Rule. Washington, DC. October 29. Document Control Number (DCN) DA00137.

ECOS. 2010. Letter to EPA: Implementing a National Vision of Mercury. Washington, DC. August 19. DCN DA00158.

ERG (Eastern Research Group). 2010. SolmeteX meeting minutes for 15 December 2010. Chantilly, VA. DCN DA00081.

ERG and Air Techniques. 2011. Notes from telephone conversation between Kimberly Landick, ERG, and Air Techniques. March 2, 2011. Subject: Amalgam Separator Questions. DCN DA00060.

ERG and American Dental Accessories. 2011. Email correspondence between Kimberly Landick, ERG, and American Dental Accessories. February 28, 2011. Subject: Request for Amalgam Separator Information. DCN DA00061.

ERG and DRNA (Dental Recycling North America). 2011. Notes from telephone conversation between Kimberly Landick, ERG, and Marc Sussman and Darwin Moreira, DRNA. March 1, 2011. Subject: Amalgam Separator Questions. DCN DA00062.

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# SECTION 4
# PROFILE OF DENTAL INDUSTRY

The industry category that would be affected by the proposed rule is Offices of Dentists (NAICS[5] 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)[6] 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 (Census, 2007a):

> "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 2007 Economic Census, which reported that there were 127,057 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 Section 10 of this document.

In addition to dental offices, dentistry can be performed at larger institutional dental service facilities (e.g., clinics or dental schools). These facilities are not included in the 2007 Economic Census data. EPA estimates that in addition to the 127,057 dental offices identified from the Economic Census, there are 130 dental institutional facilities for a total of 127,187 dental offices/facilities. EPA recognizes that additional dental practices also exist at installations operated by the federal government, specifically the Department of Defense. While EPA intends

[5] North American Industry Classification System.

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

such facilities to be subject to the proposed rule, EPA does not have information on which to base an estimate of the number of such facilities.

**Table 4-1. Number of Dental Offices by State (2007)**

| State | NAICS 621210: Dental Offices |
|---|---|
| Alabama | 1,451 |
| Alaska | 318 |
| Arizona | 2,529 |
| Arkansas | 956 |
| California | 19,973 |
| Colorado | 2,474 |
| Connecticut | 1,766 |
| Delaware | 237 |
| District of Columbia | 323 |
| Florida | 7,116 |
| Georgia | 3,231 |
| Hawaii | 689 |
| Idaho | 717 |
| Illinois | 5,768 |
| Indiana | 2,328 |
| Iowa | 1,073 |
| Kansas | 1,033 |
| Kentucky | 1,586 |
| Louisiana | 1,523 |
| Maine | 479 |
| Maryland | 2,563 |
| Massachusetts | 3,107 |
| Michigan | 4,400 |
| Minnesota | 2,037 |
| Mississippi | 870 |
| Missouri | 2,153 |
| Montana | 424 |
| Nebraska | 790 |
| Nevada | 1,033 |
| New Hampshire | 585 |
| New Jersey | 4,627 |
| New Mexico | 620 |
| New York | 9,101 |
| North Carolina | 2,885 |
| North Dakota | 259 |
| Ohio | 4,406 |
| Oklahoma | 1,376 |

**Table 4-1. Number of Dental Offices by State (2007)**

| State | NAICS 621210: Dental Offices |
|---|---|
| Oregon | 1,871 |
| Pennsylvania | 5,285 |
| Rhode Island | 409 |
| South Carolina | 1,421 |
| South Dakota | 277 |
| Tennessee | 2,170 |
| Texas | 7,959 |
| Utah | 1,491 |
| Vermont | 272 |
| Virginia | 2,948 |
| Washington | 3,281 |
| West Virginia | 566 |
| Wisconsin | 2,078 |
| Wyoming | 223 |
| **Total U.S.** | **127,057** |

Source: Census, 2007b.

**Table 4-2. Growth in Number of Dental Offices (1997 to 2007)**

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

Sources: Johnston, 2005; Census, 2007c and 2007d.

## 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 offices to place or remove amalgam. EPA is not proposing to include wastewater discharges from dental offices where the practice does not typically place or remove dental amalgam.

EPA does not have information on the number of practices that fall within each of the nine areas identified above. Rather, EPA used ADA's 2009 Survey of Dental Practice to identify the number of dental practices that are general practices or specialty practices. Based on the information provided by ADA, EPA estimates that nationally, 21 percent of the total number of dental offices (127,187) are categorized as specialty practices (ADA, 2010). EPA estimates that 65 percent of all specialty practices would fall within one of the areas that EPA is proposing not to subject to the proposed rulemaking (Vandeven and McGuiness, 2005). Therefore, EPA estimates that approximately 110,000 dental offices would be subject to the proposed 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 the 2009 DMR database, EPA identified five dental offices that have National Pollutant Discharge Elimination System (NPDES) permits. The dental offices were classified as minor dischargers. Of these, only one office reported discharge information in ICIS-NPDES. Table 4-4 summarizes the discharges reported by this office.

**Table 4-3. Dental Offices with NPDES Permits in ICIS-NPDES**

| NAICS | NPDES ID | SIC Code | Office Name | Location |
|---|---|---|---|---|
| 621210: Dental Offices | LAG531791 | 8021 | Dr. Pellegrini DDS | Madisonville, LA |
| | LAG531821 | 8021 | Medical/Dental Office Building | Mandeville, LA |
| | LAG532300 | 8021 | Johnny J. Bouzigard DDS | Cut Off, LA |
| | LAG532353 | 8021 | Bayou Dental Care | Raceland, LA |
| | MS0056901 | 8021 | Southern Training & Education | Starkville, MS |

Source: U.S. EPA, 2009.

**Table 4-4. Dental Offices with Discharge Data in ICIS-NPDES**

| NAICS | NPDES ID | Discharge (Outfall) | Pollutant | Average Concentration (mg/L) | Maximum Concentration (mg/L) | Pollutant Discharge (LBY) | Total Wastewater Flow (MGD) |
|---|---|---|---|---|---|---|---|
| 621210: Dental Offices | MS0056901 | 001 | Biochemical Oxygen Demand ($BOD_5$) | 134 | 134 | 244.92 | 0.0006 |
| | | 001 | Chlorine, total residual | 0 | 0 | 0 | 0.0006 |
| | | 001 | Coliform, fecal general | 1720 | 1720 | 3143.74 | 0.0006 |
| | | 001 | Total Suspended Solids | 37 | 37 | 67.63 | 0.0006 |

Source: U.S. EPA, 2009.
LBY – pounds per year
MGD – million gallons per day
mg/L – milligrams per liter

The lack of information in TRI and DMR about dental industry wastewater discharges 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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# SECTION 5
# DENTAL AMALGAM WASTE, POLLUTANTS OF CONCERN, AND POTW PASS THROUGH

This section discusses the sources of amalgam waste from dental offices and describes a typical office configuration. This section 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

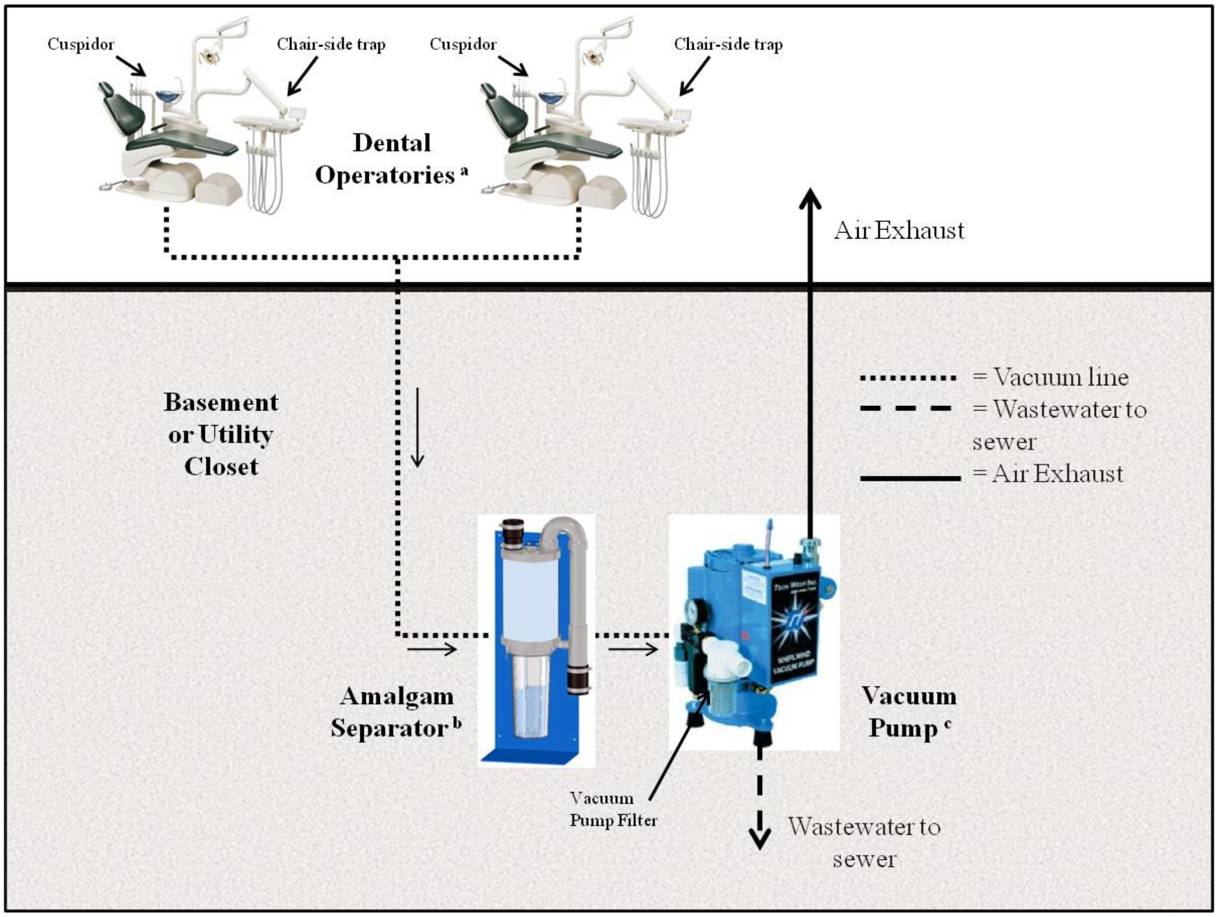
Amalgam used in dental offices is approximately 49 percent mercury, by weight, mixed with a powder of silver, tin, copper, and zinc, and small amounts of indium or palladium. The liquid mercury and metal powder mixture are often supplied in capsules, in which they are kept separate until the dentist 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 use is diminishing in the United States. Due to the increased concern regarding mercury in the environment, several U.S. industries have significantly decreased their use of mercury since the 1980s (Vandeven and McGinnis, 2005). Although dental practices have also reduced their mercury amalgam use, as of 2005, amalgam was still widely used for restorations (Vandeven and McGinnis, 2005; Stone, 2004). ADA predicts that use of amalgam will continue to decrease due to factors such as the introduction of improved filling material, decreasing tooth decay rates, and earlier detection of tooth decay (U.S. EPA, 2007).

## 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

As described above, dental amalgam is usually composed of mercury, silver, tin, copper, zinc and small amounts of indium, and palladium. Of the dental amalgam constituents, mercury is of greatest concern to human health because it is a persistent, toxic chemical that can bioaccumulate across each trophic level of the food chain. Mercury from dental amalgam makes its way into the environment when it is discharged from the dental facility to a POTW, where it settles into sewage sludge, or is discharged to surface waters. Once discharged, certain microorganisms change mercury into methylmercury, a form of mercury that can be absorbed by fish, shellfish and animals that eat fish.

EPA finds that the separation technologies considered for controlling mercury from amalgam solids will be similarly effective on the other solid metals composing amalgam. Therefore, controls installed for the reduction of mercury discharges will similarly reduce the discharge of other metals contained in amalgam.

### 5.3.1 POTW Pass Through Analysis

To establish pretreatment standards, EPA examines whether the pollutants discharged by the industry "pass through" a POTW to waters of the U.S. or interfere with the POTW operation or sludge disposal practices. EPA's consideration of pass through for national technology-based categorical pretreatment standards differs from that described in Section III of the general pretreatment standards. For categorical pretreatment standards, EPA's approach for pass through satisfies two competing objectives set by Congress: (1) that standards for indirect dischargers be equivalent to standards for direct dischargers; and (2) that the treatment capability and performance of the POTWs be recognized and taken into account in regulating the discharge of pollutants from indirect dischargers.

Generally, in determining whether pollutants pass through a POTW, EPA compares the percentage of the pollutant removed by typical POTWs achieving secondary treatment with the percentage of the pollutant removed by facilities meeting BAT[7] effluent limitations. A pollutant is deemed to pass through a POTW when the average percentage removed by a typical POTW is less than the percentage removed by direct dischargers complying with BPT[8]/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 proposed Dental Amalgam Rule, where only pretreatment standards are being developed, EPA compared the POTW removals with removals achieved by indirect dischargers using the candidate technology that otherwise satisfies the BAT factors. Historically, EPA's primary source of POTW removal data is its 1982 *Fate of Priority Pollutants in Publicly Owned Treatment Works*, also known as the 50 POTW Study (U.S. EPA, 1982). The 50 POTW study presents data on the performance of 50 POTWs performing secondary treatment to remove toxic pollutants. Results of this study demonstrated that POTWs remove 90 percent of total mercury found in wastewater. EPA received data from targeted studies performed by NACWA that indicate a POTW can remove 95 percent of total mercury (NACWA, 2007). However, these

[7] Best Available Technology Economically Achievable.

[8] Best Practicable Control Technology Currently Available.

studies reflect the performance of best performing POTWs, as opposed to the 50 POTW Study, which reflects nationwide POTWs. Consequently, for the proposed Dental Amalgam Rule, EPA maintains a POTW removal rate of 90 percent for its nationwide pass-through analysis. In comparison, indirect dischargers using the proposed technology will remove 99.0 percent or more of total mercury prior to discharge. Therefore, EPA concludes mercury passes through, and is proposing requirements to control its discharge.

For the other metal constituents[9], POTWs remove the following percentages from wastewater prior to discharge (U.S. EPA, 1982):

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

EPA concludes that these metals contained in dental amalgam, also pass through POTWs as defined above.

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[9] EPA does not have information from the 50 POTW Study to estimate the POTW removals for indium and palladium.

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# SECTION 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 MOU between EPA, the American Dental Association (ADA), and the National Association of Clean Water Agencies (NACWA) (see Section 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 19 local mandatory programs spanning six states. This section includes the following subsections:

- Section 6.1 discusses national programs.
- Section 6.2 summarizes state programs.
- Section 6.3 summarizes local programs.
- Section 6.4 presents voluntary programs.

## 6.1 NATIONAL DENTAL AMALGAM REQUIREMENTS AND GUIDANCE

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. In the past, EPA has issued guidance and other strategies to reduce releases of mercury to the environment, including discharges of dental amalgam.

### 6.1.1 U.S. EPA Strategies to Reduce Mercury Discharges

Before developing the proposed pretreatment standards, EPA and 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).

EPA regulates the disposal of mercury-containing waste under the 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.[10] 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 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 how much hazardous waste a site generates per month. Most dental practices generate less than 100 kilograms of non-acute hazardous waste per month and less than 1 kilogram of acute hazardous waste per month.[11] Such facilities are therefore classified as "Conditionally Exempt Small Quantity Generators" (CESQGs). CESQGs are not subject to most of the RCRA hazardous waste requirements, provided the waste is managed properly. However, some states have additional requirements for CESQGs or do not exempt CESQGs from all requirements (HERCenter, 2008).

### 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).

[10] 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.

[11] Elemental mercury found in dental amalgam is a non-acute hazardous waste.

### 6.1.3 <u>Food and Drug Administration</u>

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).

### 6.1.4 <u>American Dental Association</u>

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

*<u>ADA Best Management Practices</u>*

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 management and disposal of amalgam waste. These include information regarding proper recycling 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.<br>Do not flush amalgam waste down the drain or toilet.<br>Use line cleaners that minimize the dissolution of amalgam.<br>Do not use bleach or chlorine-containing cleaners to flush wastewater lines.<br>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.<br>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.<br>Store amalgam waste in a covered plastic container labeled "Amalgam for Recycling" or as directed by the recycler.<br>Store different types of amalgam (e.g., contact and non-contact) in separate containers for recycling. |

**Table 6-1. ADA BMPs for Dental Amalgam**

| Focus | Best Management Practice |
|---|---|
| Amalgam capsules | Do not use bulk elemental mercury, also referred to as liquid or raw mercury.<br>Use pre-capsulated alloys and stock a variety of capsule sizes.<br>Recycle used disposable amalgam capsules.<br>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.<br>Do not put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage.<br>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.<br>Do not put contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage.<br>Recycle teeth that contain amalgam restorations after confirming with the recycler that they will accept extracted teeth with amalgam restorations.<br>Do not dispose of extracted teeth that contain amalgam restorations in biohazard containers, infectious waste containers (red bags), sharps containers, or regular garbage.<br>Do appropriately disinfect extracted teeth that contain amalgam restorations (e.g., 10 minutes in a 1:10 bleach-to-water solution).<br>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). |
| Chair-side traps | Use chair-side traps to retain amalgam and recycle the content.<br>Do not rinse chair-side traps containing amalgam over drains or sinks.<br>Disposable traps from dental units dedicated strictly to hygiene may be placed in with the regular garbage.<br>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.<br>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.<br>Do not rinse vacuum pump filters containing amalgam, amalgam separator canisters, or other amalgam collection devices that may be used over drains or sinks.<br>Change the filter according to the manufacturer's recommended schedule.<br>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.<br>Check with licensed recycler to determine if they accept it.<br>Do not pour bulk mercury waste in the garbage, into a red bag, or down the drain.<br>Check with state regulatory agency and municipality to find out if a collection program is available. |

Source: ADA, 2007.

*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.

*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).

## 6.2 State Dental Amalgam Requirements

EPA identified 12 states as having mandatory program requirements for dental offices:

- Connecticut;

- Louisiana[12];
- Maine;
- Massachusetts;
- Michigan;
- New Hampshire;
- New Jersey;
- New York;
- Oregon;
- Rhode Island;
- Vermont; and
- Washington.

In addition to the above states, New Mexico passed a bill in 2013 that creates the Dental Amalgam Waste Reduction Act. The Act requires dental offices to remove dental amalgam from waste streams by installing an amalgam separator by December 31, 2014 that complies with international standards for removal efficiency (New Mexico Legislature, 2013).

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, NY, OR, VT, WA, and only new offices in RI).<br>Follow state BMPs (CT, LA, MA, MI, NH, NJ, NY, OR, RI, VT, WA).<br>Do not use bulk mercury (LA, NJ, NY, OR). |
| Amalgam separator technology specifications | Meet ISO Standard 11143 (CT, ME, MI, NH, NJ, NY, OR, RI, VT, WA).<br>Operate at 95% efficiency (MA, ME, MI, NY, VT).[a]<br>Operate at 98% efficiency (MA if new, ME if after 3/20/03).<br>Operate at 99% efficiency (NY if new, RI). |
| Operation specifications for amalgam separators | Must be operated at all times when dental procedures are performed (CT).<br>Must service every chair at office where amalgam waste is generated (MA).<br>New offices must have separators installed prior to opening (OR). |
| Method for demonstrating compliance | Submit separator certification to state environmental agency (CT, MA, ME, NJ).<br>Provide certification of compliance with BMPs (CT, MA, NH, NJ).<br>Maintain maintenance and servicing records and be able to provide upon request (CT, ME).<br>Provide written notice of method of disposing mercury removed by the separator (ME). |

[12] 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.

**Table 6-2. Summary of Elements of State Requirements**

| Element | Examples from State Requirements |
|---|---|
| Compliance tracking | Department of Environmental Protection (DEP) inspections (CT).<br>Web form for providing proof of compliance (RI). |

Sources: CTDEP, 2006; Louisiana Legislature, 2006; MassDEP, 2007; Maine DEP, 2005; MIDEQ, 2008; NHDES, 2002; NYDEC, 2007; Oregon State Legislature, 2007; RIDEM, 2007; VTDEC, 2006; WADOE, 2005; Walsh, 2007.
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.

Bills for dental mercury controls have been proposed but not passed in the following states:

- *Alabama*. In 2004, the Alabama State legislature began debate on two bills designed to regulate the use of mercury in dental offices: HB 495, Mercury Amalgam Filling, and HB 665, Bill to Require Dentists to Provide Information about Mercury or Mercury Amalgam to Patients. It appears that both of these bills failed to clear the House and were tabled in the House Health Committee (ALISON, 2007).

- *Arkansas*. The Mercury Poisoning Reduction Act of 2003 required the Arkansas Department of Environmental Quality to develop a plan for reducing mercury pollution from dental procedures and to implement a mandatory program for dental offices by July 1, 2004 (Arkansas, 2003). However, EPA could not find information to determine if this Act had been either enacted or enforced.

- *California*. In 2005, Assembly Bill 966, which would establish standards related to amalgam in dental and related services, passed the state Senate by a vote of 51 to 28 but was vetoed by the governor’s office (California Legislative Counsel, 2005).

Three states (Florida, Idaho, and Minnesota) 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 6-3. Mandatory BMPs by State and Comparison to ADA BMPs [a,b]

| Best Management Practice | ADA | CT | LA | MA | NH | NJ | NY | OR | RI | VT | WA |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Requirement/Guidance** | **G** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** |
| **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 | X | | |
| Recycle used disposable amalgam capsules. | 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 |
| Salvage, store and recycle non-contact amalgam (scrap 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 |
| 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 | |
| **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 | X |
| Where appropriate, disposable amalgam traps are preferable to reusable traps. | | X | | | 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 | 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 | |

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

| Best Management Practice | ADA | CT | LA | MA | NH | NJ | NY | OR | RI | VT | WA |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Requirement/Guidance** | **G** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** | **R** |
| **Amalgam Separators** | | | | | | | | | | | |
| Install and use amalgam separators. | 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; NHDES, 2002; NJR, 2007; NYDEC, 2007; RIDEM, 2007; VTDEC, 2006; and WADOE, 2005.

G — Guidance.

R — Requirement.

a — Michigan's Best Management Practices are not available online; Michigan's law requires that on or before December 31, 2013, dentists must install and use an amalgam separator on each wastewater drain in the dentist's office that is used to discharge dental amalgam. The amalgam separator must have an efficiency of 95 percent or greater as determined through testing in accordance with ISO 11143 standards (MIDEQ, 2008). Maine requires the installation and use of amalgam separators but does not require that dental offices follow the state's Best Management Practices (Maine DEP, 2005).

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).

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

| Best Management Practice | ADA | DC | FL | ID | MN |
|---|---|---|---|---|---|
| **Initial Use** | | | | | |
| Use only pre-capsulated alloys and/or stock a variety of capsule sizes. | X | X | X | X | |
| Do not use bulk mercury. | X | X | X | X | |
| **Recycling/Disposal** | | | | | |
| Manage amalgam waste through recycling as much as possible. | 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 |
| Salvage, store, and recycle non-contact amalgam (scrap amalgam). | X | X | | X | X |
| Salvage amalgam pieces from restorations after removal (contact amalgam) and recycle amalgam waste. | 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 |
| Do not put non-contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage. | 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 |
| 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 |
| **Chair-Side Traps** | | | | | |
| Use chair-side traps to retain amalgam and recycle the content. | X | X | X | X | X |
| Do not rinse chair-side traps containing amalgam over drains or sinks. | X | X | X | X | X |
| Where appropriate, disposable amalgam traps are preferable to reusable traps. | | | X | | |
| **Vacuum Pumps** | | | | | |
| Recycle contents retained by the vacuum pump filter or other amalgam collection device, if they contain amalgam. | 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 |
| 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 |
| **Amalgam Separators** | | | | | |
| Install and use amalgam separators. | 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 |

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

## 6.3 LOCAL DENTAL AMALGAM REQUIREMENTS

EPA identified and reviewed nine mandatory program requirements for the following localities:

- King County Wastewater Treatment Division (KCWTD), WA;
- East Bay Municipal Utility District (EBMUD), Oakland, CA;
- Palo Alto Regional Water Quality Control Plant (RWQCP), CA;
- Northeast Ohio Regional Sewer District (NEORSD), Cleveland, OH;
- Several Wisconsin sewerage districts: Madison, Milwaukee, Neenah-Menasha, Oshkosh, GrandChute and Menasha West, Wausau, Fond du Lac and Green Bay-De Pere, Waukesha, Watertown, Beloit, and La Crosse (Behm, 2008);
- Fort Collins and Boulder, CO;
- San Francisco, CA;
- Solon, OH; and
- Narragansett Bay, RI.

This list is not intended to be an exhaustive list of local programs. Table 6-5 summarizes the elements of the local requirements to control discharges of dental mercury. Table 6-6 compares the lists of local BMPs to ADA's BMPs. Many elements included in the local requirements are similar to those of the state requirements described in Section 6.2.

**Table 6-5. Summary of Elements of Local Requirements**

| Element | Examples from Local Requirements |
|---|---|
| Requirements | Meet a mercury discharge limit of 0.2 ppm (King County) if a separator is not installed.<br>Install amalgam separators (East Bay, Palo Alto, Wisconsin, Fort Collins, San Francisco, Solon, Narragansett Bay).<br>Alternative to installing an amalgam separator:<br>– Office must pay a fee of $1,770 per year and be subject to inspections and testing (East Bay).<br>– Office must obtain a discharge permit and monitor wastewater (San Francisco).<br>– Follow local BMPs (King County, Palo Alto, Northeast (NE) Ohio, Milwaukee, Narragansett Bay). |
| Exemptions | Offices that remove amalgam no more than three days per year (King County).<br>Certain specialty fields (King County).<br>Offices that installed separators prior to regulation (Palo Alto). |
| Technology specifications | Meet ISO Standard 11143 (King County, Madison, East Bay). |
| Method for demonstrating compliance | Provide certification for separator (East Bay, Palo Alto, Madison, Milwaukee).<br>Provide certification of compliance with BMPs (East Bay, Palo Alto, NE Ohio, Madison, Milwaukee).<br>Provide documentation of mercury waste hauling (East Bay, Palo Alto, NE Ohio). |
| Compliance tracking | Enforcement protocol including notice of violation, compliance schedule, and penalties for noncompliance (King County).<br>Inspections performed by local POTW (East Bay, Palo Alto, Madison, Milwaukee). |

Sources: EBMUD, 2005; KCWTD, 2007; MMSD, 2008; NEORSD, 2007; Palo Alto, 2007; Walsh, 2007.

**Table 6-6. Best Management Practices by Municipality**

| Best Management Practice | Municipality | | | | | | |
|---|---|---|---|---|---|---|---|
| | ADA | East Bay, Oakland, CA | King County, WA | Milwaukee and Madison, WI [a] | Narragansett Bay, RI | NE Ohio, Cleveland, OH | Palo Alto, CA |
| Requirement/Guidance | G | R | R | R | R | R | R |
| **Initial Use** | | | | | | | |
| Use only pre-capsulated alloys and/or stock a variety of capsule sizes. | X | X | | X | X | X | X |
| Do not use bulk mercury. | X | | | X | | X | X |
| **Recycling/Disposal** | | | | | | | |
| Manage amalgam waste by recycling as much as possible. | X | X | | X | | X | X |
| Recycle used disposable amalgam capsules. | X | | | X | X | X | |
| Do not flush amalgam waste down the drain or toilet. | X | X | X | X | X | X | X |
| Salvage, store, and recycle non-contact amalgam (scrap amalgam). | 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 |
| Recycle extracted 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 | 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 |
| Do not put contact amalgam waste in biohazard containers, infectious waste containers (red bags), or regular garbage. | 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 |
| **Chair-Side Traps** | | | | | | | |
| Use chair-side traps to retain amalgam and recycle the content. | 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 |
| Where appropriate, disposable amalgam traps are preferable to reusable traps. | | X | | | X (G) | X (G) | |

**Table 6-6. Best Management Practices by Municipality**

| Best Management Practice | Municipality | | | | | | |
|---|---|---|---|---|---|---|---|
| | **ADA** | **East Bay, Oakland, CA** | **King County, WA** | **Milwaukee and Madison, WI [a]** | **Narragansett Bay, RI** | **NE Ohio, Cleveland, OH** | **Palo Alto, CA** |
| **Requirement/Guidance** | **G** | **R** | **R** | **R** | **R** | **R** | **R** |
| **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 |
| Do not rinse vacuum pump filters containing amalgam or other amalgam collection devices over drains or sinks. | X | X | X | X | X | X | X |
| Use line cleaners that minimize the dissolution of amalgam. | X | X | | | X | X (G) | X |
| Do not use bleach or chlorine-containing cleaners to flush wastewater lines. | X | X | | X | X | X (G) | 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 |
| Install and use amalgam separators. | X | X | X | X | X | X | X |

Sources: ADA, 2007; EBMUD, 2005; KCWTD, 2007; NEORSD, 2007; Palo Alto, 2007; Uva, 2007; MMSD and University of Wisconsin Extension. 2006.
a — The Milwaukee and Madison programs reference BMPs developed by the Wisconsin Dental Association (MMSD and University of Wisconsin Extension. 2006).
G — Guidance.
R — Requirement.

## 6.4 VOLUNTARY PROGRAMS

Some states and localities have initiated voluntary rather than mandatory dental mercury reduction programs. The following two subsections 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 6-7 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.

### 6.4.1 Voluntary Programs with High Participation Rates

This subsection describes case studies of three voluntary programs (Duluth, MN; Wichita, KS; 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 Mercury Code of Management Practices (CMP) for the city. The CMP 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 Mercury CMP 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 Section 6.2, 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 6-7. 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 Mercury Code of Management Practices (CMP).<br>Encouraged dentists to use technologies beyond chair-side trap and vacuum filter (e.g., amalgam separator).<br>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.<br>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.<br>Dentists are responsible for cost of recycling.<br>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.<br>700 clinics participated in program.<br>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 6-7. Summary of Voluntary Programs for Reducing Dental Amalgam Releases to Wastewater**

| State (Jurisdiction) | Date | Description | Participation Rate | Verification of Participation |
|---|---|---|---|---|
| Missouri<br>(Springfield) | 2006 | University of Missouri conducted a study to determine whether voluntary BMPs could significantly reduce mercury discharges from dental offices.<br>Offered a half-day training course on BMPs.<br>Also sent outreach materials via mail to local members of the dental society.<br>Collected wastewater samples to determine mercury reductions. | 254 members in the local dental society.<br>54 (21%) of local dentists attended the half-day training session on BMPs.<br>76 (30%) of dentists indicated that they had implemented BMPs as a result of outreach.<br>Very few dentists installed amalgam separators. | UM sent a follow-up survey to the 254 members of the local dental society. |
| Oregon<br>(City of Corvallis) | 2003 | Voluntary installation of amalgam separators and implementation of BMPs.<br>Corvallis was awarded EPA's 2006 National First Place Clean Water Act Recognition Award for Pretreatment Program Excellence. | 100% | No information. |
| Washington<br>(WA Dental Association) | August 2003 | Voluntary installation of amalgam separators and implementation of other BMPs. | 80% and anticipates an additional 16% | No information. |
| Washington<br>(Seattle and King County) | No information | Significant outreach to dental offices on proper management of scrap amalgam, proper use of chair-side traps and pump filters to manage waste, and amalgam separators.<br>Participation rate was so low that King County decided to implement a mandatory program. | <50% managed scrap amalgam properly.<br>25% installed amalgam separators.<br>10% contracted with waste haulers. | King County:<br>Made unannounced visits to 212 dental offices.<br>Contacted separator vendors to obtain lists of dental office customers.<br>Contacted waste haulers and mail-away firms to obtain lists of dental office customers. |
| Wisconsin<br>(Madison) | 1997 | Encouraged use of amalgam separators through outreach to dentists.<br>Section 6.4.1 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.

### 6.4.2 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, one of the two programs discussed in this section decided to implement mandatory requirements for BMPs and amalgam separators due to the low level of participation in the voluntary program.

*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 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 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 scrap 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 6-7 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 section focuses on participation rates for the voluntary program. Section 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 scrap amalgam increased significantly after BMP training while the improper disposal decreased.
- The amount of amalgam scrap 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 Missouri/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).

### 6.4.3 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 will have higher participation rates than voluntary programs. However, over time (5 to

10 years), participation rates for well-implemented voluntary programs will be similar to participation rates for mandatory programs (Larry Walker Associates, 2002).

The highest participation percentages were seen for voluntary programs that included the threat of a mandatory second phase. 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. Often, the mandatory second phase of the program was not ultimately implemented. 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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# SECTION 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 Section 5, chair-side traps and vacuum pumps 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. Finally, as described in Section 6, best management practices (BMPs) are integral to reducing pollutants in dental discharges.

This section describes amalgam separators and polishing, including information on treatment efficiency. 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 (such as 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.[13] 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 dumping out the solid particles collected by them into a bucket or other storage container, then properly disposing of the dental amalgam waste (ERG and SolmeteX, 2011). 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, 2007a). Virtually all amalgam separators currently on the market use sedimentation processes (with or without filtration) to settle out the solids from the wastewater. 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 (Fan et al., 2002). Baffles or tanks can reduce the speed of the wastewater flow, allowing more amalgam particles to settle out.

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

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 Section 7.2.

Although none of the separators that EPA identified in the literature review added chemicals to enhance solids removal, chemical and polymer additions have been effective in precipitating a portion of dissolved mercury out of dental wastewater (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. 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

Two standards are currently used to evaluate the treatment efficiency of amalgam separators: (1) International Organization for Standardization (ISO) Standard 11143; and (2) U.S. EPA's Environmental Technologies Verification (ETV) program.

ISO Standard 11143. The majority of amalgam separators currently on the market have been evaluated for their ability to meet ISO 11143, the international standard for amalgam separators used in connection with dental equipment. ISO 11143 calls for measuring amalgam separator efficiency by evaluating the retention of amalgam. 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.

ISO Standard 11143 requires that an amalgam separator remove at least 95 percent by weight of amalgam particles (i.e., the 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 is important to note that certification under 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 determine 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 the 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 particulate mercury removal efficiencies for the three technologies ranged from 95 to 99.9 percent. However, the study also noted that an effluent 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 39 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.[14] As illustrated, all separators exceeded the ISO Standard of 95 percent efficiency, 34 separators exceeded 97 percent efficiency, and 29 separators exceeded 99 percent efficiency of amalgam particle removal. The separators described in Table 7-1 achieved an average efficiency of 98.8 percent and a median efficiency of 99.0 percent.

**Table 7-1. Efficiency and Technology of 39 Amalgam Separators**

| Model | Manufacturer | Treatment Technology | Percentage of Amalgam Removed (by weight) [a] | Data Sources |
|---|---|---|---|---|
| A 1250 | Air Techniques | Centrifugation | >99.0% | 6 |
| 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 Boss | Hygenitek | Sedimentation, filtration, ion exchange | 99.2% | 1,9 |
| Amalgam Collector CE18 | R & D Services | Sedimentation | 99.6% | 1,9 |
| Amalgam Collector CE24 | R & D Services | Sedimentation | >99.9% | 1,10 |
| Amalgam Collector CH12 | R & D Services | Sedimentation | >99.9% | 1,10 |
| Amalgam Collector CH9 | 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 1000 Plus | Rebec Solutions | Sedimentation | 99.0% | 1,13 |
| Catch 400 Plus | Rebec Solutions | Sedimentation | 99.0% | 1,13 |
| Catch 9000 Plus | Rebec Solutions | Sedimentation | 99.0% | 1,13 |
| ECO II | Metasys, distributed by Pure Water Development | Sedimentation | 97.5% | 1,4,5,10 |

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

**Table 7-1. Efficiency and Technology of 39 Amalgam Separators**

| Model | Manufacturer | Treatment Technology | Percentage of Amalgam Removed (by weight) [a] | Data Sources |
|---|---|---|---|---|
| Hg5 | SolmeteX | Sedimentation, filtration, chemical binding | 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% | 1,15 |
| Merc II | Bio-Sym Medical | Sedimentation, filtration, ion exchange | 98.2% | 5,9 |
| MRU10 | Dental Recycling North America | Sedimentation, filtration, ion exchange | >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 |
| MSS 2000 | Maximum Separation Systems | Sedimentation, filtration | 98.9% | 2,4,5 |
| MSS 601 | Maximum Separation Systems | Sedimentation, filtration | 95.0% | 3,5 |
| Rasch 890-1000 | AB Dental Trends | Sedimentation, filtration, ion exchange | 98.9% | 2,9 |
| Rasch 890-1500 | AB Dental Trends | Sedimentation, filtration, ion exchange | 98.0% | 1,16,17 |
| Rasch 890-4000 | AB Dental Trends | Sedimentation, filtration, ion exchange | >99.9% | 2,4 |
| Rasch 890-6000 | AB Dental Trends | Sedimentation, filtration, ion exchange | 98.0% | 1,16,17 |
| Rasch 890-7000 | AB Dental Trends | Sedimentation, filtration, ion exchange | 98.0% | 1,16,17 |
| Rasch AD-1500 | American Dental Accessories | Sedimentation | 95.0% | 1,5 |
| REM2000 Series/Catch 1000 | Rebec Solutions | Sedimentation | 99.7% | 1,13 |
| REM2000 Series/Catch 400 | Rebec Solutions | Sedimentation | 99.6% | 1,13 |
| REM2000 Series/Catch 9000 | Rebec Solutions | Sedimentation | 99.6% | 2,13 |
| **Median** | | | **99.0%** | |

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.

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) – ERG and Air Techniques, 2011; (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, (15) MARS Bio Med Processes, 2012; (16) Haraldsson and Nyman, 2001; (17) Haraldsson and Nyman, 2003.[Summary of analysis included in ERG, 2014].

## 7.2 POLISHING

Mercury is both dissolved and suspended in dental amalgam. More than 99.6 percent is suspended (Stone, 2004). An additional process (sometimes referred to as polishing) uses ion exchange to remove dissolved mercury. In contrast to amalgam separators that contain an ion exchange component in the same unit (as discussed in the previous section), polishing ion exchange refers to a separate 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 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 in order for the resin (or other capturing material) to capture the dissolved mercury. As a result, EPA concludes this sequential polishing approach, in which amalgam separators and ion exchange are separate units, is more effective than the single units described above that combine sedimentation and ion exchange to remove both suspended and dissolved mercury. 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, ISO certification testing is based on an evaluation of the removal of amalgam 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 to 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 facilities that were responding to sanitation district concerns over their mercury discharges. In both cases, the polishing systems were installed (as is usual) to treat wastewater after it left the amalgam separator.

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 not surprising since, as indicated above, dissolved mercury is 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 also found limited data on the costs of polishing systems (ERG, 2011a).

## 7.3 BEST MANAGEMENT PRACTICES

Most state and local dental mercury reduction programs include BMPs. Most are based on the American Dental Association's BMPs developed in 2003 (ADA, 2007b), discussed in

6.1.4. After reviewing ADA's BMPs and those of state and local programs, EPA decided to include certain operational, maintenance, and inspection practices in its proposed rule because these practices have a significant impact on how effectively amalgam separators function to achieve their certified performance levels.

EPA proposes to require line cleaners that do not contain bleach and are of neutral pH. Bleach and other corrosive cleaners can solubilize bound mercury. If dental practices use corrosive cleaners to clean vacuum lines leading 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).

EPA's second proposed BMP prohibits the flushing of scrap amalgam (contact and non-contact) into drains that do not lead to an amalgam separator (e.g., a cuspidor not attached to the vacuum line), and into general use sinks. Sources of dental amalgam include, but are not limited to, chair-side traps, screens, vacuum pump filters, dental tools, or collection devices. This rule limits additional avenues through which mercury might be discharged from dental offices.

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# SECTION 8
# REGULATORY OPTIONS

EPA identified one technology that is available and has been demonstrated to control dental amalgam discharges from the Dental Category: amalgam separators. EPA further identified best management practices (BMPs) that would ensure the effectiveness of the technology and would further reduce discharges of dental amalgam not captured by an amalgam separator.

## 8.1 PRETREATMENT STANDARDS FOR EXISTING SOURCES (PSES)

EPA developed one option based on proper operation and maintenance of amalgam separators that achieve a 99.0 percent reduction of amalgam from amalgam process wastewater,[15] along with BMPs. Dental offices can comply with the numeric pretreatment standard for existing sources (i.e., 99.0 percent reduction in amalgam discharges) by installation, proper operation, and proper maintenance of an amalgam separator certified to meet 99.0 percent reduction of total mercury according to the 2008 ISO 11143 standard. Compliance with two additional BMPs — not flushing scrap amalgam down the drain and cleaning of chair-side traps with non-bleach, non-chlorine cleaners — are necessary to prevent mercury discharges that would bypass the separator. Dental offices would also be able to meet the standard by certifying that they do not place or remove amalgam.[16]

EPA finds that the proposed 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. The American Dental Association (ADA) recommends its dentists to use the technology on which the rule is based (i.e., amalgam separators and BMPs). Further, 40 percent of dental offices use amalgam separators on a voluntary basis or are in states with state or local laws requiring the use of amalgam separators. For those dental offices that have not yet installed an amalgam separator, EPA estimates that this is a low-cost technology with an approximate average annual cost of $700 per office[17] (U.S. EPA, 2011). EPA’s economic analysis of these costs in relation to the overall income of the regulated entities show that this proposed rule is economically achievable (see Section 10). Finally, EPA also examined the non-water-quality environmental impacts of the proposed rule and found them to be acceptable (see Section 14).

EPA is not proposing to establish pretreatment standards based on technologies that remove dissolved mercury, i.e., polishing. None of the states with mandated requirements to reduce dental mercury discharges requires polishing. EPA also lacks adequate performance data to assess the efficacy of polishing or its availability for nationwide use. EPA’s current information suggests that polishing only achieves incremental removals over the selected

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

[16] Dentists that elect to certify that they do not install or remove amalgam will be exempt from any further requirements of the proposed rule. See 40 CFR 441.10. EPA recognizes that dentists, infrequently, may remove amalgam in the course of emergency treatment. EPA does not intend for discharges of dental amalgam, related to only to these infrequent emergency treatments, to preclude such dentists from certifying.

[17] This estimate reflects the average annualized cost for dentists that do not currently have amalgam separators.

amalgam separator technology of less than one-half percent of total mercury (Garcia, 2009). While very small amounts of mercury can have environmental effects, EPA lacks sufficient evidence to assert that adding polishing technology to amalgam separation will result in mercury discharge reductions that have a discernible environmental impact greater than the reductions achieved by amalgam separation alone. EPA estimates that the capital costs of amalgam separators and polishing are at least 4 times that of amalgam separators alone (ERG, 2011). Finally, EPA is uncertain whether existing dental offices have adequate space to install polishing controls. These factors led EPA to find that polishing is not “available” as that term is used in the CWA. As a result, EPA did not select amalgam separators followed by polishing as the technology basis for the proposed rule.

### 8.1.1 Requirements

The proposed rule would establish a pretreatment standard that would require removal of at least 99.0 percent of total mercury from amalgam discharges and require dental offices to follow BMPs. Affected dental offices would be able to meet the standard by using, properly operating, and maintaining a dental amalgam separator certified to achieve at least 99.0 percent reduction of total mercury according to the 2008 ISO 11143 standard, to perform certain BMPs, and to certify to this effect. Dental offices could also meet the standard by certifying that they do not install or remove amalgam except in limited emergency circumstances. As a point of clarification, dentists that elect to certify that they do not install or remove amalgam will be exempt from any further requirements of the proposed rule.

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

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

The proposed rule would subject all dentists (except certain specialists as described in Section 4.2) to categorical pretreatment requirements. EPA recognizes that some dentists potentially subject to the proposal do not apply or remove dental amalgam except, possibly, in limited emergency circumstances. However, EPA, in consultation with pretreatment authorities, has been unable to determine a publicly available source of information that would enable identification of dental offices where dental amalgam may reasonably be expected not to be present. As such, the proposed rule would apply to such dischargers and require them to report baseline information, but it would also allow them to certify (at any time) that they do not and will not install or remove amalgam (not including infrequent emergency treatment). This would fulfill their obligations under the proposed rule. If they subsequently elect to install or remove amalgam, they would then need to comply with the proposed numeric standard (e.g., proper operation and maintenance of an amalgam separator) and with the BMPs in the proposed rule.

EPA does not want to penalize existing dental offices or institutional dental facilities that have already installed amalgam separators voluntarily or to comply with state or local requirements. EPA recognizes that these offices may currently have amalgam separators in place that are certified to a removal rate slightly lower than the proposed standard. For example, some states require dental offices to employ amalgam separators that are certified to remove 95 percent total mercury. EPA's proposed rule does not require existing separators with a remaining useful life to be retrofitted with new separators. EPA chose to avoid imposing additional costs on dental facilities that moved ahead of EPA's proposed requirements to install a treatment technology, and also chose to avoid the additional solid waste that would be generated by disposal of existing separators. Therefore, EPA is proposing that, as long as they continue to properly operate and maintain existing separators, comply with BMPs, and comply with recordkeeping requirements, these facilities would be considered in compliance with the numeric standard until 10 years from the effective date of the final rule. EPA selected 10 years because it appears to be a conservative estimate of the useful life of the existing equipment. However, if a currently installed separator needs to be replaced before 10 years have elapsed, these facilities would need to install and operate an amalgam separator that meets the proposed removal efficiency of at least 99.0 percent.

## 8.2 PRETREATMENT STANDARDS FOR NEW SOURCES (PSNS)

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

EPA does not propose to establish more stringent requirements for new sources based on technologies that remove dissolved mercury (i.e., polishing) for the same reasons stated above for existing standards. New sources would need to comply with the requirements discussed in Section 8.1.1.

## 8.3 REFERENCES

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# SECTION 9
# COSTS OF TECHNOLOGIES

This section provides information on EPA's approach for estimating compliance costs for dental offices. EPA's cost methodology assumes dental offices would use the required best management practices (BMPs) in combination with 2008 ISO 11143 amalgam separators on the market today to comply (see Section 7.1.2). EPA categorized all of the costs as either capital costs (one-time costs associated with planning or installation of technologies), as operations and maintenance (O&M) costs (costs that occur on a regular ongoing basis such as inspection or cleaning of the unit or annual purchases of amalgam cartridges), or as reporting costs. Cost estimates are expressed in terms of 2010 dollars.

## 9.1 METHODOLOGY FOR DEVELOPING MODEL DENTAL OFFICE COSTS

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

In general, one approach that EPA sometimes takes to estimate compliance costs is to use facility-specific data to determine what requirements apply to a given facility and whether that facility would already meet the proposed requirements. This approach requires substantial facility-specific technical and financial data. In the case of the Dental Category, EPA would need such data for approximately 110,000 dental offices estimated to be subject to this proposed 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, thereby modeling the full universe of affected facilities.

EPA used the model approach to estimate the costs to affected dental offices of complying with the proposed Dental Amalgam Rule. The model approach includes calculating compliance costs for dental offices based on the number of chairs at the practice (i.e., by size classes of dental offices). EPA developed compliance costs for six models based on the numbers of chairs in an office. The ranges for each model are: 1 to 2 chairs, 3 chairs, 4 chairs, 5 chairs, 6 chairs, and 7+ chairs (average of 10 chairs). In addition to each of the size class models, EPA developed a model facility to represent very large offices such as clinics and universities. The costs for large facilities is discussed separately in Section 10.

EPA developed two sets of costs for each model: one for dental offices that do not currently operate an amalgam separator and one for dental offices with that treatment technology in place.

### 9.1.1 Model Compliance Costs for Dental Offices Without Amalgam Separators

For offices that do not currently operate an amalgam separator, EPA estimated capital costs and O&M costs. Capital costs include the purchase of the amalgam separator and installation. Recurring costs include replacement of the cartridge and other O&M costs such as maintenance supply costs; inspection costs; maintenance costs; recycling preparation; and recycling costs.

The costs of amalgam separators varies, but is relative to the size (number of chairs) of the dental practice. The number of amalgam separators required depends on the number of chairs in an office and the amalgam separator model. Wastewater flow rate determines how often filters and traps need to be cleaned/replaced (Walsh, 2007). Manufacturer suggested retail prices (MSRP) for an amalgam separator range from $210 to $3,984 (depending on the size of the dental office). Table 9-1 provides a summary of costs of commercially available amalgam separator systems (non-inclusive), including specific O & M costs for each model (in 2010 dollars).

Installation costs will also vary depending on the existing configuration of the dental office. Based on conversations with amalgam separator vendors, EPA estimated plumbing modifications for initial installation would cost $250, regardless of the size of the office (ERG, 2010.

**Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2010)**

| Model | Manufacturer | MSRP | Maintenance | Replacement Parts | Recycling | Reference |
|---|---|---|---|---|---|---|
| A1250 | Air Techniques | $1,000 | Replace filter every 6–12 months. | Filter: $250 | Not included in MSRP | 7 |
| AD-1000 | American Dental Accessories | $809 | Replace filter every 18 months. | Filter: $504 | Not included in MSRP | 2 |
| Amalgam Boss | M.A.R.S. Bio-Med Processes | $1,015 | Unit switch out after 2 years for 1 chair, 1.5 years for 2–3 chairs and 1 year for 4–10 chairs. | Separator unit: $1,015 | Included in MSRP | 1, 3 |
| Amalgam Collector — CE18 | R & D Services | $839–$1,220 | Recycle every 3 years; adjust liquid level tube every 6 months. | Not available | Recycling service: $254 | 1 |
| Amalgam Collector — CE24 | R & D Services | $1,265–$1,647 | Recycle every 3 years; adjust liquid level tube every 6 months. | Not available | Recycling service: $305 | 1 |
| Amalgam Collector — CH12 | R & D Services | $605–$986 | Recycle every 4 years; adjust liquid level tube every 6 months. | Not available | Recycling service: $305 | 1 |
| Amalgam Collector — CH9 | R & D Services | $626–$1,020 | Recycle every 3 years; adjust liquid level tube every 6 months. | Not available | Recycling service: $316 | 2, 4 |
| ARU-10 | Hygenitek | $770–$803 | Replace ion cartridge every 6 months, replace settlement tank every 2 years. | Cartridge, settling tanks: $179 | Included in MSRP | 5, 6 |
| Asdex AS-10 | Capsule Technologies | $233 | Replace filter every 6–8 months. | Filter: $99 | Not included in MSRP | 1 |
| Asdex AS-20 | Capsule Technologies | $332 | Replace cartridge every 6–8 months. | Cartridge: $198 | Not included in MSRP | 1 |
| Asdex AS-20 | American Dental Accessories | $300 | Replace filter every 6–12 months. | Filter: $177 | Not included in MSRP | 1, 8 |
| Asdex AS-9 | American Dental Accessories | $210 | Replace filter every 6 months. | Filter: $80 | Not included in MSRP | 8 |
| BU10 | Dental Recycling North America | $762 | Replace canister every 12 months. | Canister: $508 | Included in MSRP | 1, 9 |

**Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2010)**

| Model | Manufacturer | MSRP | Maintenance | Replacement Parts | Recycling | Reference |
|---|---|---|---|---|---|---|
| BU30 | Dental Recycling North America | $1,418 | Replace canister every 12 months. | Canister: $762 | Included in MSRP | 1, 9 |
| Catch 1000 Plus | Rebec Solutions | $2,042 | Replace canister every 12 months. | Canister: $656 (price is for 2 canisters) | Included in MSRP | 1, 10 |
| Catch 400 Plus | Rebec Solutions | $1,204 | Replace canister every 12 months. | Canister: $656 (price is for 2 canisters) | Included in MSRP | 1, 10 |
| Catch 9000 Plus | Rebec Solutions | $3,984 | Replace canister every 12 months. | Canister: $910 (price is for 3 canisters) | Included in MSRP | 1, 10 |
| ECO II | Pure Water Development | $570 | Replace canister every 12 months. | Canister: $209 | Not included in MSRP | 1 |
| Hg5 | SolmteX | $762 | Replace cartridge every 6–12 months. | Cartridge: $304 | Included in MSRP | 1, 11 |
| Hg5 High Volume | SolmeteX | $2,500 | Replace cartridge every 12 months. | Cartridge: $170–$285 | Not included in MSRP | 1, 11 |
| Hg5 Mini | SolmeteX | $762 | Replace cartridge every 6–12 months. | Cartridge: $304 | Included in MSRP | 1, 11 |
| Liberty Boss | M.A.R.S. Bio-Med Processes | $1,574 | Unit switch out after 3 years for 1–3 chairs, 2 years for 4–10 chairs, 1 year for 11–17 chairs. | Separator unit: $1,574 | Included in MSRP | 1 |
| Merc II | Bio-Sym Medical | $1,300 | Replace cartridge every 12 months. | Cartridge: $495 | Included in MSRP | 5 |
| MRU10 | Dental Recycling North America | $1,250 | Replace canister every 12 months. | Canister: $1,195 | Included in MSRP | 2, 9 |
| MRU30 | Dental Recycling North America | $1,795 | Replace canister every 12 months. | Canister: $1,395 | Included in MSRP | 9 |
| MSS 1000 | Maximum Separation Systems | $1,288 | Replace settling tank every 12 months. | Settling tank: $178 | Not included in MSRP | 2, 3 |

**Table 9-1. Cost of Purchasing, Operating, and Maintaining Amalgam Separators ($2010)**

| Model | Manufacturer | MSRP | Maintenance | Replacement Parts | Recycling | Reference |
|---|---|---|---|---|---|---|
| MSS 2000 | Maximum Separation Systems | $1,418 | Replace settling tank every 12–18 months. | Settling tank: $168 | Not included in MSRP | 2 |
| MSS 601 | Maximum Separation Systems | $1,167 | Replace settling tank every 12 months. | Settling tank: $178 | Not included in MSRP | 3 |
| Rasch 890-1000 | AB Dental Trends | $1,251 | Replace canister every 12–18 months | Canister: $627 | Included in MSRP | 2, 4 |
| Rasch 890-1500 | AB Dental Trends | $731 | Replace canister every 12–18 months | Canister: $627 | Included in MSRP | 1, 4 |
| Rasch 890-4000 | AB Dental Trends | $1,352–$1,931 | Replace canister every 18 months | Canister: $660–$1,319 | Included in MSRP | 2 |
| Rasch 890-6000 | AB Dental Trends | $700 | Replace canister every 12–18 months | Canister: $628 | Included in MSRP | 1, 4 |
| Rasch 890-7000 | AB Dental Trends | $1,132 | Replace canister every 12–18 months. | Canister: $627 | Included in MSRP | 1, 4 |
| Rasch AD-1500 | American Dental Accessories | $675 | Replace filter every 18 months. | Filter: $470 | Included in MSRP | 1, 8 |
| REM2000 Series/Catch 1000 | Rebec Solutions | $2,028 | Replace cartridge every 12 months. | Cartridge: $452 | Included in MSRP | 1, 10 |
| REM2000 Series/Catch 400 | Rebec Solutions | $1,204 | Replace cartridge every 12 months. | Cartridge: $452 | Included in MSRP | 1, 10 |
| REM2000 Series/Catch 9000 | Rebec Solutions | $3,984 | Replace cartridge every 12 months. | Cartridge: $808 | Included in MSRP | 2, 10 |
| **Average Cost for 1 to 2 Chairs** | | **$408–$596** | | **$195** | | |
| **Average Cost for 3 to 5 Chairs** | | **$552–$645** | | **$231** | | |
| **Average Cost for 6 Chairs** | | **$1,055-$1,060** | | **$430** | | |
| **Average Cost for 7+ Chairs** | | **$1,509-$1,552** | | **$629-$664** | | |

Sources: (1) – U.S. Air Force, 2011; (2) – MCES, 2009; (3) – MMSD and University of Wisconsin--Extension, 2006; (4) – ADA, 2007; (5) – McManus and Fan, 2003; (6) – SF Environment, 2005; (7) – ERG and Air Techniques, 2011; (8) – ERG and American Dental Accessories, 2011; (9) – ERG and DRNA, 2011; (10) – ERG and Rebec Solutions, 2011; (11) – ERG and SolmeteX, 2011b.

Table 9-2 provides a summary of the one-time model facility costs for dental offices that do not currently use amalgam separators. The separator purchase cost for the various chair sizes in the average of the range provided in Table 9-1.

**Table 9-2. Summary of One Time Costs ($2010) to Model Dental Offices Without Amalgam Separators**

| Cost Element | Number of chairs in the model dental office | | | |
|---|---|---|---|---|
| | 1 or 2 | 3, 4, or 5[a] | 6 | 7+ |
| **Separator Purchase** | $502 | $599 | $1,058 | $1,531 |
| **Installation** | $250 | $250 | $250 | $250 |

Sources: See Table 9-1; ERG, 2010

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

EPA also estimated annual costs which include O&M costs and separator replacement costs. Operation and maintenance costs include the following:

- *Inspection and maintenance*: The proposal would require that the separator be inspected at least monthly. EPA included costs for a dental assistant ($17/hr[18]) to perform a five minute visual inspection monthly for all dental office sizes. The proposed rule would also require the separator to be maintained regularly. For all dental office sizes, EPA assumed maintenance would be performed by a dental assistant every two weeks and that each maintenance session would take 15 minutes.

- *Recycling preparation*: Most separators require that their solids collectors and/or filters be replaced at least every 12 months. EPA assumed that a dental assistant ($17/hr) would spend 15 minutes two times per year preparing materials for shipping and recycling for all dental office sizes.

- *Recycling service costs*: The range of recycling service costs provided by vendors is $0 (some include recycling costs as part of the original purchase cost) to $316 per recycling event (see Table 9-1). Assuming a conservative estimate of recycling every two years, the maximum annual cost for recycling service is $158 per year. EPA estimated recycling costs as the average of the range ($0 to $158), or $79 per year, for all dental office sizes (ERG, 2014).

For separator replacement costs, EPA estimated that amalgam separators would have a service life of ten years, after which time the amalgam separator would need to be replaced. See Section 10.2.1.

Table 9-3 provides a summary of annual model facility costs for dental offices that do not currently use amalgam separators.

[18] Bureau of Labor Statistics reported a wage of $16.41 per hour for this job category in May 2011 (Bureau of Labor Statistics, 2011). EPA rounded up to $17 per hour.

**Table 9-3. Summary of Annual Costs ($2010) to Model Dental Offices Without an Amalgam Separator**

| Cost Element | Number of chairs in the model dental office | | | |
|---|---|---|---|---|
| | 1 or 2 | 3, 4, or 5[a] | 6 | 7+ |
| Replacement Parts | $195 | $219 | $430 | $647 |
| O & M including recycling | $216 | $216 | $216 | $216 |

Sources: See Table 9-1; U.S. EPA, 2011b.

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

### 9.1.2 Model Compliance Costs for Dental Offices Currently Using Amalgam Separators

EPA also differentiated costs at the office level based on whether offices already have amalgam separators in place. EPA assumed that offices with treatment in place will incur no cost for purchasing and installing compliance technology at the time of initial regulatory compliance. However, EPA estimated additional permit-related costs (see Section 10.2) and some recurring incremental costs for such offices. Specifically, EPA assumed that dental offices with technology-in-place would incur recurring costs in relation to the costs otherwise incurred by offices without technology-in-place, as shown in Table 9-4 and Table 9-5.

**Table 9-4. Percentage of Recurring Costs Incurred by Dental Offices Currently Using Amalgam Separators**

| Cost Category | Percentage of Costs Incurred[a] |
|---|---|
| Replacement parts | 50 percent |
| Amalgam separator maintenance | 50 percent |
| Amalgam separator operation | 100 percent |
| Recycling preparation and recycling service cost | 50 percent |

[a] The percentage of costs estimated to be incurred by offices with technology-in-place relative to costs estimated to be incurred by office without technology-in-place.
Source: U.S. EPA, 2011b.

**Table 9-5. Summary of Annual Model Facility Costs ($2010) to Dental Offices Currently Using Amalgam Separators**

| Cost Element | Number of chairs in the model dental office | | | |
|---|---|---|---|---|
| | 1 or 2 | 3, 4, or 5[a] | 6 | 7+ |
| Replacement Parts | $98 | $110 | $215 | $324 |
| O & M including recycling | $116 | $116 | $116 | $116 |

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

## 9.2 REPORTING REQUIREMENTS AND BMP COSTS

All dental offices subject to the proposed Dental Amalgam Rule will have reporting requirements and BMP requirements. EPA included reporting costs for one-time preparation of a baseline report and initial compliance report[19] and recurring costs associated with preparation of an annual certification statement. EPA estimates that an office or dental assistant would require the following times to complete each report:

- 76 minutes to complete the baseline monitoring report;
- 51 minutes to complete the initial compliance report; and
- 49 minutes to complete the annual certification statement.

As has been mentioned, EPA recognizes that some dental offices subject to the proposed rule do not place or remove amalgam and has proposed a provision that allows non-users of amalgam to submit a one-time baseline monitoring report to certify that they do not use amalgam except in unusual emergency circumstances. Should the status of a non-using dental office change, the certification would no longer be valid. For example, if a dental office so certifies and is sold, the new owner must similarly so certify or would need to comply with the rule. See CFR 441.10.

Assuming a labor rate of $17 per hour for a dental assistant (based on Bureau of Labor Statistics for May 2011), EPA estimates that the cost to complete the baseline monitoring report is $22, the cost to complete the initial compliance report is $15, and the cost to complete the annual certification is $14 (U.S. EPA, 2011a).

EPA did not include incremental costs for BMPs because (1) costs for non-oxidizing, pH neutral line cleaners are roughly equivalent to other line cleaners; and (2) dentists will not incur additional costs by changing the location for flushing scrap amalgam.

## 9.3 METHODOLOGY FOR DEVELOPING COSTS FOR INSTITUTIONAL FACILITIES

Institutional dental service facilities (e.g., clinics or dental schools), have a larger number of chairs than the typical dental office. For these institutional dental facilities, EPA developed a costing methodology based on the methodology for offices described above. For purposes of costs, EPA assumed the average institutional facility has 15 chairs. In the methodology described previously, the model practice with the largest number of chairs for which EPA developed cost information is the 7+ chair model with an average of 10 chairs. EPA estimated that these facilities would incur compliance technology costs in the same categories as other facilities, with compliance equipment costs being 50 percent greater than those incurred by facilities in the 7+ chairs category. All other costs are the same as those incurred by facilities in the 7+ chairs category (U.S. EPA, 2011b). These costs are likely overstated as they do not reflect opportunities the largest offices may have to share costs,[20] and they do not assume any economies of scale. Section 10 provides further details on costs developed for larger dental facilities.

## 9.4 REFERENCES

ADA (American Dental Association). 2007. ADA Professional Product Review. Document Control Number (DCN) DA00043.

[19] These are required under 40 CFR 403.

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

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# SECTION 10
# ECONOMIC IMPACTS FOR THE DENTAL INDUSTRY

This section describes EPA's economic impact assessment of the proposed Dental Amalgam Rule, and is organized as follows:

- Section 10.1 reviews the structure of the regulated sector in terms of number of dental offices potentially subject to the proposed Dental Amalgam Rule and the distribution of these offices by revenue.
- Section 10.2 presents the compliance costs that EPA expects would be incurred by dental offices under the proposed rule.
- Section 10.3 combines the estimates of numbers of in-scope offices by relevant operating characteristics to estimate total nationwide compliance costs for the proposed rule.
- Section 10.4 assesses the social cost of the proposed Dental Amalgam Rule, including costs to dental offices (and facilities)[21] and the costs to permitting authorities for administering rule requirements.
- Section 10.5 determines the potential for significant economic impact on small dental office entities as a result of the proposed rule.

## 10.1 Overview of Dental Offices Potentially Subject to Proposed Regulation

In this section, EPA reviews its estimate of the number of dental offices that might be within the scope of the proposed 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 facilities using mercury-containing materials (dental amalgam); (2) the number of dental facilities that currently use treatment technology; and (3) as a result, the costs likely to be incurred by dental offices in complying with the proposed rule.

### 10.1.1 Number of Dental Offices Potentially Subject to the Proposed Regulation

To support the assessment of total costs and economic impact of the proposed Dental Amalgam Rule, EPA relied on data from the 2007 Economic Census describing the number of firms and establishments in the dental office sector (NAICS 621210), and their annual receipts (revenue). EPA used the 2007 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

[21] As explained in Section 2, dental offices include but are not limited to institutions, permanent or temporary offices, clinics, mobile units, home offices, and facilities, including dental facilities owned and operated by Federal, state or local governments.

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 proposed Dental Amalgam Rule. Therefore, EPA estimated compliance costs for each dental office size. In addition, in reviewing the 2007 Economic Census data for the dental office sector, EPA observed that almost all firms are single-establishment/single-office firms. The total of 127,057 establishments/offices is owned by 121,048 firms — thus no more than 6,009 firms, or fewer than 5 percent of firms, can be 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 2007 Economic Census counts of dental offices, EPA applied a number of adjustments to estimate the number of dental offices, in aggregate and by revenue range, that could be within the scope of the proposed Dental Amalgam Rule:

- As shown in Table 10-1, the Economic Census listed 127,057 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 2007 dollars. EPA performed its cost and economic impact analysis based on 2010 dollar values. Because the Economic Census revenue ranges are defined in 2007 dollars, EPA adjusted these dollar values defining the revenue ranges to 2010 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 2007 and 2010 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 2007–2010 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 127,057 total offices, the Economic Census reported 116,792 offices as being in business for the full 2007 year and 10,265 offices as being in business for only part of the year. The numbers of dental offices listed in the 11 revenue ranges represent the 116,792 offices that were in business for the full 2007 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 10,265 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 proposed Dental

Amalgam Rule. The tenth revenue range includes the Small Business Administration revenue cutoff ($7.0 million), and EPA assigned none of the partial-year offices to this range.[22] 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 ($2007) | | Revenue Ranges ($2010) | | Number Establishments | Adjusted Number Establishments[a] |
|---|---|---|---|---|---|
| Low | High | Low | High | | |
| 0 | $10,000 | 0 | $10,448 | 160 | 174 |
| $10,000 | $24,999 | $10,449 | $26,120 | 471 | 513 |
| $25,000 | $49,999 | $26,121 | $52,242 | 940 | 1,023 |
| $50,000 | $99,999 | $52,243 | $104,485 | 2,401 | 2,613 |
| $100,000 | $249,999 | $104,486 | $261,213 | 13,034 | 14,183 |
| $250,000 | $499,999 | $261,214 | $522,427 | 28,766 | 31,303 |
| $500,000 | $999,999 | $522,428 | $1,044,856 | 42,803 | 46,578 |
| $1,000,000 | $2,499,999 | $1,044,857 | $2,612,141 | 25,046 | 27,255 |
| $2,500,000 | $4,999,999 | $2,612,142 | $5,224,283 | 2,783 | 3,028 |
| $5,000,000[b] | $9,999,999 | $5,224,284 | $10,448,567 | 330 | 330 |
| $10,000,000 | Or more | $10,448,568 | Or more | 58 | 58 |
| Establishments operated for the entire year | | | | 116,792 | 127,057 |
| Establishments not operated for the entire year | | | | 10,265 | - |
| **Total Establishments** | | | | **127,057** | **127,057** |

Sources: Census, 2007; U.S. EPA, 2011c.
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 130 large institutional dental facilities (e.g., clinics or dental schools, see Section 4.1). Adding these 130 facilities to the 127,057 dental offices from the Economic Census brings the total of dental offices and facilities that are potentially within the rule's scope to 127,187.

### 10.1.2 Adjustments to Account for Baseline Status

EPA also accounted for additional factors that will influence the extent to which dental office sector would incur costs under the proposed Dental Amalgam Rule:

- First, EPA recognized that certain specialty dental practices do not place or remove dental amalgam (see Section 4.2) and thus did not include them in the scope of the proposed 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. Within this group of specialty practices, approximately 65 percent *do not* place or remove dental amalgam (ADA, 2010a; Vandeven and McGinnis, 2005). As a result, of the total of dental offices, EPA estimated that approximately 14 percent are

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

specialists that would not be subject to the proposed rule.[23] Because the proposed rule would not apply to them, EPA assigned no compliance-related costs to these 17,215 offices, and these offices are not included in the impacts analysis (U.S. EPA, 2011c).

- Second, EPA divided the in-scope offices 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. From a review of state requirements, EPA estimates that 40 percent of offices have amalgam separators in place already, and used this percentage to categorize offices as technology-in-place offices and no-technology-in-place offices (U.S. EPA, 2011a).

- Third, among the remaining 60 percent of offices that have not already installed amalgam separators, EPA estimated that approximately 20 percent of these dental offices do not place or remove dental amalgam (Pimpare, 2012) and thus would incur no treatment technology-related costs due to the proposed Dental Amalgam Rule. These 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 facilities, with these further breakouts. EPA carried these estimated numbers of dental offices and large facilities by baseline amalgam use and compliance status forward to the cost and economic impact analysis.

[23] $0.21 \times 0.65 \approx 0.135$. See U.S. EPA, 2011a, for further information on this estimate.

**Table 10-2. Adjusting Office Counts to Account for Baseline Amalgam Use and Technology in Place**

| Revenue Ranges ($2010) (see Table 10-1) | | Number of Offices | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | No-Technology-In-Place | | |
| Low | High | Total (see Table 10-1) | Not Using Amalgam | Using Amalgam | Technology-In-Place | Total | With Technology Costs | No Technology Costs |
| 0 | $10,448 | 174 | 24 | 151 | 61 | 90 | 72 | 18 |
| $10,449 | $26,120 | 513 | 69 | 443 | 179 | 264 | 211 | 53 |
| $26,121 | $52,242 | 1,023 | 138 | 884 | 358 | 527 | 421 | 105 |
| $52,243 | $104,485 | 2,613 | 354 | 2,259 | 913 | 1,346 | 1,077 | 269 |
| $104,486 | $261,213 | 14,183 | 1,920 | 12,264 | 4,958 | 7,305 | 5,844 | 1,461 |
| $261,214 | $522,427 | 31,303 | 4,237 | 27,066 | 10,943 | 16,123 | 12,898 | 3,225 |
| $522,428 | $1,044,856 | 46,578 | 6,304 | 40,273 | 16,282 | 23,991 | 19,193 | 4,798 |
| $1,044,857 | $2,612,141 | 27,255 | 3,689 | 23,566 | 9,528 | 14,038 | 11,230 | 2,808 |
| $2,612,142 | $5,224,283 | 3,028 | 410 | 2,619 | 1,059 | 1,560 | 1,248 | 312 |
| $5,224,284 | $10,448,567 | 330 | 45 | 285 | 115 | 170 | 136 | 34 |
| $10,448,568 | Or more | 58 | 8 | 50 | 20 | 30 | 24 | 6 |
| Total Economic Census | | 127,057 | 17,198 | 109,859 | 44,416 | 65,443 | 52,355 | 13,089 |
| Institutional Facilities | | 130 | 18 | 112 | 45 | 67 | 54 | 13 |
| Total | | 127,187 | 17,215 | 109,972 | 44,462 | 65,510 | 52,408 | 13,102 |
| Percentage adjustment factors | | | 13.5% | 86.5% | 40.4% | 59.6% | 80.0% | 20.0% |

Sources: Census, 2007 and U.S. EPA, 2011c.

## 10.2 SUMMARY OF THE PROPOSED 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 proposed rule.

### 10.2.1 Summary of Compliance Costs

Using the methodology described in Section 9, EPA developed compliance costs for model facilities with and without amalgam separators. As described in Section 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 Section 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 six number-of-chair ranges, as follows:

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

EPA also estimated costs for the large institutional facilities (such as clinics or universities). For purposes of costs, EPA assumed the average institutional facility has 15 chairs. See Section 9.3 for more details.

Table 10-3 lists estimated compliance costs for offices that have and have not already installed amalgam separators, in 2010 dollars, by cost category and by size (i.e., number of chairs). A size category for large facilities (which average 15 chairs) is also included.

**Table 10-3. Dental Office Compliance Costs by Cost Category and Number of Chairs (2010 dollars)**

| Cost Element | No-Technology-In-Place<br>Operating Size: Number of Chairs and Large Facilities | | | | | | | Technology-In-Place<br>Operating Size: Number of Chairs and Large Facilities | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1–2 | 3 | 4 | 5 | 6 | 7+ | Large Fac. | 1–2 | 3 | 4 | 5 | 6 | 7+ | Large Fac. |
| **Technology Installation and Other Startup Costs** | | | | | | | | | | | | | | |
| Equipment purchase | $502 | $599 | $599 | $599 | $1,058 | $1,531 | $2,297 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| Installation | $250 | $250 | $250 | $250 | $250 | $250 | $250 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| One-time baseline monitoring report (BMR) | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 | $22 |
| One-time compliance report | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 | $15 |
| **Annual Costs** | | | | | | | | | | | | | | |
| Replacement parts | $195 | $219 | $219 | $219 | $430 | $647 | $647 | $98 | $110 | $110 | $110 | $215 | $324 | $324 |
| Separator maintenance | $111 | $111 | $111 | $111 | $111 | $111 | $111 | $55 | $55 | $55 | $55 | $55 | $55 | $55 |
| Recycling preparation | $9 | $9 | $9 | $9 | $9 | $9 | $9 | $4 | $4 | $4 | $4 | $4 | $4 | $4 |
| Recycling service | $79 | $79 | $79 | $79 | $79 | $79 | $79 | $40 | $40 | $40 | $40 | $40 | $40 | $40 |
| Visual Inspection | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 |
| Annual certification | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 |

Source: U.S. EPA, 2011c.

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 dental offices would incur ongoing expenses in the same way as described in the preceding paragraphs and Table 10-3.

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.**[24] 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 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 seven percent, which is intended to represent the opportunity cost of capital to society, on a pre-tax, constant dollar basis.[25] The resulting present value is then annualized over the full 20-year analysis period at the seven percent interest rate. EPA used the resulting total annualized compliance costs in assessing the total estimated cost and impact of the proposed rule to dental offices, as described in subsequent sections. Table 10-3 and Table 10-4 report specific elements of compliance costs and summarize the tabulation of costs to develop estimates of the total annualized compliance cost to dental offices.

Table 10-4, below, summarizes the tallying of these costs according to the initial installation and reinstallation specifications, and present value and annualized cost calculations, as described above. 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 seven percent discount rate. The resulting annualized costs include all of the cost elements except for operational and annual certification costs, which are tallied in the final part of the table. Because these costs are incurred annually and do not vary by technology-in-place status, they are simply added to the annualized cost values in Table 10-4 to calculate the total annualized costs to dental offices and large facilities for the proposed rule.

[24] Where year 1 would be the first year in which a facility complies with the rule.

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

**Table 10-4. Summary of Annualized Compliance Costs for a Dental Office or Large Facility, Accounting for Initial Installation and Reinstallation of Amalgam Separators, and Operational and Certification Costs**

| | No-Technology-In-Place | | | | | | | Technology-In-Place | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Operating Size: Number of Chairs and Large Facilities | | | | | | | Operating Size: Number of Chairs and Large Facilities | | | | | | |
| **Cost Element** | **1–2** | **3** | **4** | **5** | **6** | **7+** | **Large Fac.** | **1–2** | **3** | **4** | **5** | **6** | **7+** | **Large Fac.** |
| **Initial Installation Analysis** | | | | | | | | | | | | | | |
| Total initial outlay | $789 | $886 | $886 | $886 | $1,345 | $1,818 | $2,584 | $37 | $37 | $37 | $37 | $37 | $37 | $37 |
| Total annual (recurring) costs | $393 | $417 | $417 | $417 | $628 | $845 | $845 | $197 | $209 | $209 | $209 | $314 | $423 | $423 |
| Present value total annual (recurring) | $2,760 | $2,929 | $2,929 | $2,929 | $4,411 | $5,935 | $5,935 | $1,380 | $1,464 | $1,464 | $1,464 | $2,205 | $2,967 | $2,967 |
| Total present value, at year 1 | $3,549 | $3,815 | $3,815 | $3,815 | $5,756 | $7,753 | $8,519 | $1,417 | $1,502 | $1,502 | $1,502 | $2,243 | $3,005 | $3,005 |
| **Reinstallation Analysis — Equipment Reinstalled at Beginning of Year 11** | | | | | | | | | | | | | | |
| Total initial outlay (0.5 installation charge) | $664 | $761 | $761 | $761 | $1,220 | $1,693 | $2,459 | $664 | $761 | $761 | $761 | $1,220 | $1,693 | $2,459 |
| Total annual (recurring) costs | $393 | $417 | $417 | $417 | $628 | $845 | $845 | $197 | $209 | $209 | $209 | $314 | $423 | $423 |
| Present value total annual (recurring) | $2,760 | $2,929 | $2,929 | $2,929 | $4,411 | $5,935 | $5,935 | $1,380 | $1,464 | $1,464 | $1,464 | $2,205 | $2,967 | $2,967 |
| Total present value, at year 11 | $3,424 | $3,690 | $3,690 | $3,690 | $5,631 | $7,628 | $8,394 | $2,044 | $2,226 | $2,226 | $2,226 | $3,426 | $4,661 | $5,426 |
| Total present value, at year 1 | $1,741 | $1,876 | $1,876 | $1,876 | $2,862 | $3,878 | $4,267 | $1,039 | $1,131 | $1,131 | $1,131 | $1,741 | $2,369 | $2,758 |
| **Combining Initial Installation and Re-Installation** | | | | | | | | | | | | | | |
| Sum, present values at year 1 | $5,290 | $5,691 | $5,691 | $5,691 | $8,618 | $11,631 | $12,785 | $2,456 | $2,633 | $2,633 | $2,633 | $3,984 | $5,374 | $5,763 |
| Annualized cost over 20 years | $499 | $537 | $537 | $537 | $814 | $1,098 | $1,207 | $232 | $249 | $249 | $249 | $376 | $507 | $544 |
| **Including Operational and Certification** | | | | | | | | | | | | | | |
| Visual Inspection | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 | $17 |
| Annual certification | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 | $14 |
| **Total Annualized Cost** | **$531** | **$569** | **$569** | **$569** | **$845** | **$1,129** | **$1,238** | **$263** | **$280** | **$280** | **$280** | **$408** | **$539** | **$575** |

Present values and annualized costs are calculated using a 7 percent discount rate. All costs are on a pre-tax basis, in 2010 dollars, and as of the time of compliance by complying entities. The social cost analysis uses an additional 3 percent discount rate and applies a different discounting treatment.

Source: U.S. EPA, 2011c.

As discussed in Section 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 proposed Dental Amalgam Rule. Although these offices will not incur treatment technology-related compliance costs, they will incur the cost of the one-time baseline monitoring report to document that they do not use amalgam in their operations. EPA estimates this cost to be $22 for each of these offices/facilities. In calculating the total compliance cost for the proposed rule, this value is annualized using the discount rate and number of periods for non-recurring outlays, and added to the total rule costs for offices and facilities 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 Section 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, 2010b). This study, called the "ADA National Study" below, indirectly reports a distribution of number of chairs by office.

Table 10-5 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 10-5. 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% |

**Table 10-5. Distribution of the Number of Chairs in Dental Offices**

| Number of Chairs in Office | Frequency | Relative Frequency | Running Total, Frequency |
|---|---|---|---|
| 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% |

Sources: ADA, 2009, 2010b.

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.[26] 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 10-6 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 large institutional facilities. Large institutional facilities are not included in this tally because EPA possesses no information on their revenue.

[26] 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 10-6. Number of Chairs in Dental Offices by Revenue Range

| Revenue Range Values ($2010) (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 Percent from ADA Distribution |
| **Using ADA Colorado Study Distribution** | | | | | | | | | | |
| 0 | $10,448 | 174 | 0.1% | 0.1% | 1–2 | 174 | 174 | 0.1% | 0.1% | 9.74% |
| $10,449 | $26,120 | 513 | 0.4% | 0.5% | 1–2 | 513 | 687 | 0.4% | 0.5% | |
| $26,121 | $52,242 | 1,023 | 0.8% | 1.4% | 1–2 | 1,023 | 1,710 | 0.8% | 1.4% | |
| $52,243 | $104,485 | 2,613 | 2.1% | 3.4% | 1–2 | 2,613 | 4,322 | 2.1% | 3.4% | |
| $104,486 | $193,476 | 14,183 | 11.2% | 14.6% | 1–2 | 8,053 | 12,376 | 6.3% | 9.7% | |
| $193,477 | $261,213 | | | | 3 | 6,130 | 18,506 | 4.8% | 14.6% | 35.06% |
| $261,214 | $478,568 | 31,303 | 24.6% | 39.2% | 3 | 26,047 | 44,552 | 20.5% | 35.1% | |
| $478,569 | $522,427 | | | | 4 | 5,256 | 49,808 | 4.1% | 39.2% | 64.29% |
| $522,428 | $879,904 | 46,578 | 36.7% | 75.9% | 4 | 31,871 | 81,680 | 25.1% | 64.3% | |
| $879,905 | $1,044,856 | | | | 5 | 14,706 | 96,386 | 11.6% | 75.9% | 78.57% |
| $1,044,857 | $1,242,938 | 27,255 | 21.5% | 97.3% | 5 | 3,445 | 99,831 | 2.7% | 78.6% | |
| $1,242,939 | $1,868,020 | | | | 6 | 10,870 | 110,700 | 8.6% | 87.1% | 84.42% |
| $1,868,021 | $2,612,141 | | | | 7+ | 12,940 | 123,641 | 10.2% | 97.3% | 100.00% |
| $2,612,142 | $5,224,283 | 3,028 | 2.4% | 99.7% | 7+ | 3,028 | 126,669 | 2.4% | 99.7% | |
| $5,224,284 | $10,448,567 | 330 | 0.3% | 99.9% | 7+ | 330 | 126,999 | 0.3% | 99.9% | |
| $10,448,568 | Or more | 58 | 0.1% | 100.00% | 7+ | 58 | 127,057 | 0.1% | 100.00% | |
| **Total[27]** | | **127,057** | **100.00%** | | — | **127,057** | | **100.00%** | | |
| **Using ADA National Study Distribution** | | | | | | | | | | |
| 0 | $10,448 | 174 | 0.1% | 0.1% | 1–2 | 174 | 174 | 0.1% | 0.1% | 12.46% |
| $10,449 | $26,120 | 513 | 0.4% | 0.5% | 1–2 | 513 | 687 | 0.4% | 0.5% | |
| $26,121 | $52,242 | 1,023 | 0.8% | 1.4% | 1–2 | 1,023 | 1,710 | 0.8% | 1.4% | |
| $52,243 | $104,485 | 2,613 | 2.1% | 3.4% | 1–2 | 2,613 | 4,322 | 2.1% | 3.4% | |
| $104,486 | $231,731 | 14,183 | 11.2% | 14.6% | 1–2 | 11,515 | 15,838 | 9.1% | 12.5% | |
| $231,732 | $261,213 | | | | 3–4 | 2,668 | 18,506 | 2.1% | 14.6% | 55.88% |
| $261,214 | $522,427 | 31,303 | 24.6% | 39.2% | 3–4 | 31,303 | 49,808 | 24.6% | 39.2% | |
| $522,428 | $760,147 | 46,578 | 36.7% | 75.9% | 3–4 | 21,194 | 71,002 | 16.7% | 55.9% | |
| $760,148 | $1,044,856 | | | | 5–6 | 25,383 | 96,386 | 19.9% | 75.9% | 82.63% |
| $1,044,857 | $1,539,698 | 27,255 | 21.5% | 97.3% | 5–6 | 8,605 | 104,991 | 6.8% | 82.6% | |

[27] The total 127,057 offices include the entire dental industry, including those dental specialists discussed in Section 4.2 that are outside the scope of the proposed rule.

## Table 10-6. Number of Chairs in Dental Offices by Revenue Range

| Revenue Range Values ($2010) (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 Percent from ADA Distribution** |
| $1,539,699 | $2,612,141 | | | | 7+ | 18,650 | 123,641 | 14.7% | 97.3% | 100.00% |
| $2,612,142 | $5,224,283 | 3,028 | 2.4% | 99.7% | 7+ | 3,028 | 126,669 | 2.4% | 99.7% | |
| $5,224,284 | $10,448,567 | 330 | 0.3% | 99.9% | 7+ | 330 | 126,999 | 0.23% | 99.9% | |
| $10,448,568 | Or more | 58 | 0.1% | 100.00% | 7+ | 58 | 127,057 | 0.1% | 100.00% | |
| **Total** | | **127,057** | **100.00%** | | — | **127,057** | | **100.00%** | | |

Source: U.S. EPA, 2011c.

## 10.3 ESTIMATED COST OF COMPLIANCE TO DENTAL OFFICES

To estimate the total nationwide cost of compliance to dental offices of the proposed rule, EPA multiplied the estimated total annualized cost of rule compliance by the number of chairs for dental offices (see Section 10.1.2). For large institutional facilities, compliance costs are multiplied by the estimated number of facilities in the resulting size ranges (see Table 10-6 and Table 10-8). 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 entities— dental offices and large institutional facilities—as of the year of compliance.

EPA completed these calculations separately for the two distributions of offices by number of chairs. Table 10-7 summarizes the results from these calculations. These total compliance cost estimates include the one-time compliance costs for dental offices that do not process dental amalgam, as described in Section 10.2.1.

**Table 10-7. Annualized Costs to Complying Dental Offices by Number of Chairs**

<table>
<tr><th colspan="3">Annualized Cost (Millions, $2010) for Alternative Number-of-Chairs Distributions</th></tr>
<tr><th>Number of Chairs</th><th>Colorado Survey</th><th>ADA Survey</th></tr>
<tr><td>1–2 chairs</td><td>$3.8</td><td>$4.9</td></tr>
<tr><td>3 chairs</td><td>$10.7</td><td rowspan="2">$18.3</td></tr>
<tr><td>4 chairs</td><td>$12.3</td></tr>
<tr><td>5 chairs</td><td>$6.0</td><td rowspan="2">$16.7</td></tr>
<tr><td>6 chairs</td><td>$5.3</td></tr>
<tr><td>7+ chairs</td><td>$10.7</td><td>$14.4</td></tr>
<tr><td>Large facilities</td><td>$0.1</td><td>$0.1</td></tr>
<tr><td>Total Costs</td><td>$49.0</td><td>$54.5</td></tr>
</table>

Present values and annualized costs are calculated using a 7 percent discount rate. All costs are on a pre-tax basis, in $2010, and as of the time of compliance by complying entities.
Source: U.S. EPA, 2011c.

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 estimates 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/facilities.

### 10.3.1 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 proposed rule to current (or pre-rule) dental office revenues (Section 10.3.1.1). In addition, EPA chose to examine the financial impacts of the proposed rule using two measures that utilize the data EPA has on dental office baseline assets and estimated replacement capital costs: (1) ratio of the proposed rule's capital costs to total dental office capital assets (Section 10.3.1.2); and (2) ratio of the proposed rule's capital costs to annual dental office capital replacement costs (Section 10.3.1.3).

#### 10.3.1.1 Cost-to-Revenue Analysis

The cost-to-revenue measure compares the annualized cost of regulatory compliance, at a seven 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 Section 10.5 below.

EPA framed the cost-to-revenue analysis around the revenue range/number-of-chairs combinations, as developed in Table 10-6, and the total annualized compliance costs that would occur within each of these analysis combinations. Table 10-8 summarizes these analytic combinations. Note that EPA was not able to perform the cost-to-revenue impact analysis for large institutional facilities, 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 large institutional facilities.

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 proposed Dental Amalgam 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 10-8. Revenue Range/Number-of-Chairs Combinations for Cost Impact Analysis**

| Revenue Range/Number of Chairs Combinations | | | Number of Offices | Percent of Total Offices |
|---|---|---|---|---|
| Low | High | Number of Chairs | | |
| **Using ADA Colorado Study Distribution** | | | | |
| 0 | $10,448 | 1–2 | 151 | 0.1% |
| $10,449 | $26,120 | 1–2 | 443 | 0.4% |
| $26,121 | $52,242 | 1–2 | 884 | 0.8% |
| $52,243 | $104,485 | 1–2 | 2,259 | 2.1% |
| $104,486 | $193,476 | 1–2 | 6,963 | 6.3% |
| $193,477 | $261,213 | 3 | 5,300 | 4.8% |
| $261,214 | $478,568 | 3 | 22,521 | 20.5% |
| $478,569 | $522,427 | 4 | 4,545 | 4.1% |
| $522,428 | $879,904 | 4 | 27,557 | 25.1% |
| $879,905 | $1,044,856 | 5 | 12,716 | 11.6% |
| $1,044,857 | $1,242,938 | 5 | 2,978 | 2.7% |
| $1,242,939 | $1,868,020 | 6 | 9,399 | 8.6% |
| $1,868,021 | $2,612,141 | 7+ | 11,189 | 10.2% |
| $2,612,142 | $5,224,283 | 7+ | 2,619 | 2.4% |

**Table 10-8. Revenue Range/Number-of-Chairs Combinations for Cost Impact Analysis**

| Revenue Range/Number of Chairs Combinations | | | Number of Offices | Percent of Total Offices |
|---|---|---|---|---|
| Low | High | Number of Chairs | | |
| $5,224,284 | $10,448,567 | 7+ | 285 | 0.3% |
| $10,448,568 | Or more | 7+ | 50 | 0.1% |
| | **Total** | | **109,859** | **100.00%** |
| **Using ADA National Study Distribution** | | | | |
| 0 | $10,448 | 1–2 | 151 | 0.1% |
| $10,449 | $26,120 | 1–2 | 443 | 0.4% |
| $26,121 | $52,242 | 1–2 | 884 | 0.8% |
| $52,243 | $104,485 | 1–2 | 2,259 | 2.1% |
| $104,486 | $231,731 | 1–2 | 9,957 | 9.1% |
| $231,732 | $261,213 | 3–4 | 2,307 | 2.1% |
| $261,214 | $522,427 | 3–4 | 27,066 | 24.6% |
| $522,428 | $760,147 | 3–4 | 18,325 | 16.7% |
| $760,148 | $1,044,856 | 5–6 | 21,948 | 20.0% |
| $1,044,857 | $1,539,698 | 5–6 | 7,440 | 6.8% |
| $1,539,699 | $2,612,141 | 7+ | 16,125 | 14.7% |
| $2,612,142 | $5,224,283 | 7+ | 2,619 | 2.4% |
| $5,224,284 | $10,448,567 | 7+ | 285 | 0.3% |
| $10,448,568 | Or more | 7+ | 50 | 0.1% |
| | **Total** | | **109,859**[28] | **100.00%** |

Source: U.S. EPA, 2011c.

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

[28] The total 109,859 dental offices are all in-scope dental offices for the proposed Dental Amalgam Rule as described in Section 10.1.2. The total does not include large facilities as noted in this section.

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 proposed 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 2007 Economic Census reports that approximately 700 offices of the approximately 110,000 total offices had revenue of less than $25,000 (2007 dollar basis; 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 proposed 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 (Section 10.3.1.3, below). Specifically, in this analysis, EPA estimated that one- to two-chair offices would incur capital replacement costs of approximately $23,500 per year (the estimated annual cost of keeping equipment in good working order) (U.S. EPA, 2011c). This outlay would exceed or represent a very substantial fraction of 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 $23,500 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 proposed 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. Table 10-9 and Table 10-10 summarize the results from this analysis. Table 10-9 reports the results by technology-in-place status; Table 10-10 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 507 dental offices would incur costs exceeding one percent of revenue, representing 0.5 percent of dental offices expected to incur costs under the proposed regulation. No offices incur costs exceeding three percent of revenue. With the *baseline set-aside offices* included in the analysis, EPA estimates that 965 dental offices would incur costs exceeding one percent of revenue, representing 0.9 percent of dental offices expected to incur costs under the proposed rule; 221 offices are estimated to incur costs exceeding three percent of revenue, representing 0.2 percent of offices expected to incur costs under the proposed 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 $7.0 million. This finding is relevant for Section 10.5.

**Table 10-9. Cost-to-Revenue Impact Summary**

| **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** | | | | | | | |
| 33 | 474 | 507 | 0.5% | 0 | 0 | 0 | 0.0% |

**Table 10-9. Cost-to-Revenue Impact Summary**

| 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 |
| **Including Baseline Set-Aside Offices in Analysis** | | | | | | | |
| 243 | 722 | 965 | 0.9% | 51 | 169 | 221 | 0.2% |

Calculations exclude the estimated 13,000 offices with no-technology-in-place that do not place or remove dental amalgam (and thus will incur only a minimal one-time reporting cost).
Percentages of affected offices are calculated as a fraction of total offices estimated to incur costs under the proposed Dental Amalgam Rule.
Source: U.S. EPA, 2011c.

**Table 10-10. Cost-to-Revenue Impact Summary by Number of Chairs**

| 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 | 507 | 4.2% | — | 0.0% | 965 | 7.9% | 221 | 1.8% |
| 3 chairs | — | 0.0% | — | 0.0% | — | 0.0% | — | 0.0% |
| 4 chairs | — | 0.0% | — | 0.0% | — | 0.0% | — | 0.0% |
| 5 chairs | — | 0.0% | — | 0.0% | — | 0.0% | — | 0.0% |
| 6 chairs | — | 0.0% | — | 0.0% | — | 0.0% | — | 0.0% |
| 7+ chairs | — | 0.0% | — | 0.0% | — | 0.0% | — | 0.0% |
| Total | 507 | 0.5% | — | 0.0% | 965 | 0.9% | 221 | 0.2% |

Percentages of affected offices are calculated as a fraction of total offices estimated to incur costs under the proposed Dental Amalgam Rule.
Source: U.S. EPA, 2011c.

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 proposed rule would not have a material adverse impact on the dental office sector.

#### 10.3.1.2 Ratio of the Proposed Rule's Capital Costs to Total Dental Office Capital Assets

From the preceding analysis, EPA found that the proposed 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 proposed Dental Amalgam 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 section, 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 the next section (Section 10.3.1.3), 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 proposed 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)[29] 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 section. 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 Section 10.3.1.1, 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 10-11 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 the large institutional facilities, 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 large institutional facilities.

**Table 10-11. Comparing Total Initial Outlay to Baseline Assets**

| Initial Compliance Outlay as Percentage of Baseline Assets (Outlay-to-Assets, OTA) | | | | |
|---|---|---|---|---|
| **Excluding Baseline Set-Aside Offices from Analysis** | | | | |
| **Number of Chairs** | **Technology-in-Place** | | **No Technology-in-Place** | |
| | **Low** | **High** | **Low** | **High** |
| 1–2 chairs | 0.1% | 0.1% | 2.7% | 1.3% |
| 3 chairs | 0.0% | 0.0% | 0.8% | 0.5% |
| 4 chairs | 0.0% | 0.0% | 0.5% | 0.3% |
| 5 chairs | 0.0% | 0.0% | 0.3% | 0.2% |

[29] 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 10-11. Comparing Total Initial Outlay to Baseline Assets**

| Initial Compliance Outlay as Percentage of Baseline Assets (Outlay-to-Assets, OTA) | | | | |
|---|---|---|---|---|
| **Excluding Baseline Set-Aside Offices from Analysis** | | | | |
| **Number of Chairs** | **Technology-in-Place** | | **No Technology-in-Place** | |
| | **Low** | **High** | **Low** | **High** |
| 6 chairs | 0.0% | 0.0% | 0.3% | 0.2% |
| 7+ chairs | 0.0% | 0.0% | 0.2% | 0.2% |
| Total | 0.0% | 0.0% | 0.7% | 0.4% |
| **Including Baseline Set-Aside Offices in Analysis** | | | | |
| | **Technology-in-place** | | **No Technology-in-place** | |
| Number of Chairs | **Low** | **High** | **Low** | **High** |
| 1–2 chairs | 0.2% | 0.1% | 3.7% | 1.7% |
| 3 chairs | 0.0% | 0.0% | 0.8% | 0.5% |
| 4 chairs | 0.0% | 0.0% | 0.5% | 0.3% |
| 5 chairs | 0.0% | 0.0% | 0.3% | 0.2% |
| 6 chairs | 0.0% | 0.0% | 0.3% | 0.2% |
| 7+ chairs | 0.0% | 0.0% | 0.2% | 0.2% |
| Total | 0.0% | 0.0% | 0.8% | 0.5% |

Source: U.S. EPA, 2011c.

With baseline set-asides excluded from the analysis, the resulting 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. With baseline set-asides included in the analysis, the resulting initial capital costs to total capital assets values are low, with an average value 0.5 percent to 0.8 percent for the 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.

#### 10.3.1.3 Ratio of the Proposed Rule's Capital Costs to Annual Dental Office Capital Replacement Costs

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 proposed 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. 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 10-12).

- 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 section of Table 10-13. "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 10-12. The second section of Table 10-13, "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 section of Table 10-13, "Steady State Annual Replacement Outlay, by Equipment Life Category," reports the results from this step.

**Table 10-12. Composition of Dental Equipment for Six-Chair Office by Equipment Life**

| | Percent of Value by Service Life Category | | | |
|---|---|---|---|---|
| **Useful Life Category** | **Major Items** | **Percent** | **Small Items** | **Percent** |
| 3 | $0 | 0.0% | $19,800 | 21.5% |
| 5 | $52,300 | 21.5% | $0 | 0.0% |
| 10 | $79,125 | 32.6% | $72,138 | 78.5% |
| 12 | $6,850 | 2.8% | $0 | 0.0% |
| 15 | $104,545 | 43.1% | $0 | 0.0% |
| **Total** | $242,820 | 100.0% | $91,938 | 100.0% |

Based on 6-chair office specifications from Georgetown University, 2003.

**Table 10-13. Initial and Annual Replacement Outlay for Startup Dental Office by Number of Chairs**

| | Number of Chairs | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **1–2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| **Initial Outlays** | | | | | | | | |
| Major items | $165,036 | $185,234 | $219,220 | $253,207 | $287,193 | $321,179 | $355,166 | $389,152 |
| Small items | $39,082 | $52,218 | $68,195 | $84,172 | $100,149 | $116,126 | $132,103 | $148,080 |
| **Total** | **$204,553** | **$237,452** | **$287,415** | **$337,379** | **$387,342** | **$437,305** | **$487,269** | **$537,232** |
| **Initial Outlays by Equipment Life Category** | | | | | | | | |
| 3 | $8,417 | $11,246 | $14,687 | $18,127 | $21,568 | $25,009 | $28,450 | $31,891 |
| 5 | $35,640 | $39,897 | $47,217 | $54,537 | $61,857 | $69,177 | $76,498 | $83,818 |
| 10 | $84,585 | $101,332 | $124,943 | $148,554 | $172,165 | $195,776 | $219,387 | $242,998 |
| 12 | $4,668 | $5,225 | $6,184 | $7,143 | $8,102 | $9,061 | $10,019 | $10,978 |
| 15 | $71,243 | $79,752 | $94,384 | $109,017 | $123,650 | $138,282 | $152,915 | $167,548 |
| **Total** | **$204,553** | **$237,452** | **$287,415** | **$337,379** | **$387,342** | **$437,305** | **$487,269** | **$537,232** |
| **Steady State Annual Replacement Outlay, by Equipment Life Category** | | | | | | | | |
| 3 | $2,806 | $3,749 | $4,896 | $6,042 | $7,189 | $8,336 | $9,483 | $10,630 |
| 5 | $7,128 | $7,979 | $9,443 | $10,907 | $12,371 | $13,835 | $15,300 | $16,764 |
| 10 | $8,459 | $10,133 | $12,494 | $14,855 | $17,216 | $19,578 | $21,939 | $24,300 |
| 12 | $389 | $435 | $515 | $595 | $675 | $755 | $835 | $915 |
| 15 | $4,750 | $5,317 | $6,292 | $7,268 | $8,243 | $9,219 | $10,194 | $11,170 |
| **Total** | **$23,531** | **$27,613** | **$33,641** | **$39,668** | **$45,696** | **$51,723** | **$57,751** | **$63,778** |

Source: U.S. EPA, 2011c.

As the final step in this analysis, EPA compared the estimated total initial outlay for the proposed Dental Amalgam Rule to the estimated steady state annual replacement outlay values, from Table 10-13. Table 10-14 reports the results from this comparison. As shown in Table 10-14 the values for initial compliance outlay as a percentage of replacement outlay are quite low, ranging from 2.2 percent to 3.5 percent, with a weighted average of 2.9 percent across all number-of-chair ranges.

**Table 10-14. Comparing Total Initial Compliance Outlay to Steady State Annual Replacement Outlay by Number of Chairs (Section 10.3.1.3)**

| | Number of Chairs | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **1–2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **Weighted Average** |
| Initial compliance outlay | $789 | $886 | $886 | $886 | $1,345 | $1,818 | $1,818 | $1,818 | |
| Baseline annual replacement outlay | $23,531 | $27,613 | $33,641 | $39,668 | $45,696 | $51,723 | $57,751 | $63,778 | |
| Initial compliance outlay as percentage of replacement outlay | 3.4% | 3.2% | 2.6% | 2.2% | 2.9% | 3.5% | 3.1% | 2.9% | 2.9% |

Source: U.S. EPA, 2011c.

**Table 10-15. Comparing Total Initial Compliance Outlay to Initial Outlay by Number of Chairs (Section 10.3.1.4)**

| | Number of Chairs | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **1–2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **Weighted Average** |
| Initial compliance outlay | $789 | $886 | $886 | $886 | $1,345 | $1,818 | $1,818 | $1,818 | |
| Initial outlay | $204,553 | $237,452 | $287,415 | $337,379 | $387,342 | $437,305 | $487,269 | $537,232 | |
| Initial compliance outlay as percentage of office startup costs | 0.4% | 0.4% | 0.3% | 0.3% | 0.3% | 0.4% | 0.4% | 0.3% | 0.3% |

Source: U.S. EPA, 2011c.

#### 10.3.1.4 Economic Impact for New Sources

EPA assessed whether the proposed 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 10-13. EPA then compared the initial compliance cost for dental offices as estimated in Section 10.2 to these startup values. This comparison demonstrates that the amalgam separator capital costs would represent only 0.3 percent to 0.4 percent of the cost of starting a dental office and, therefore, do not pose a barrier to entry (see Table 10-15 above).

## 10.4 SOCIAL COST OF THE PROPOSED DENTAL AMALGAM RULE

The previous sections reviewed the estimated costs of the proposed Dental Amalgam Rule to dental offices and facilities and assessed the potential impact of the proposed rule on these offices and facilities. This section reviews the costs of the proposed Dental Amalgam 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 Section 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 seven percent for developing present and annualized values. As described previously, the seven 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, three 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 three and seven 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 proposed Dental Amalgam 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, 2012, and the compliance period three years following promulgation, in 2015[30]. 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

[30] EPA completed its economic impact analysis assuming a promulgation date of 2012. EPA does not expect the results of the social cost analysis would significantly change due to a later promulgation date.

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 2015, or the first year of required compliance, are then discounted an additional three years to 2012, 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, based on 2007 Economic Census values expressed in 2010 dollars, 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 Section 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, 2012, and using three percent and seven percent discount rates. Table 10-16 summarizes these cost values for the proposed rule by the alternative number-of-chair distributions.

**Table 10-16. Compliance Costs on a Social Cost Basis for Proposed Dental Amalgam Rule**

| Annualized Cost (Millions, $2010) as of 2012, Year of Rule Promulgation | | | | |
|---|---|---|---|---|
| | Using 3 Percent Discount Rate | | Using 7 Percent Discount Rate | |
| | Colorado Survey | ADA Survey | Colorado Survey | ADA Survey |
| Compliance cost | $43.6 | $48.5 | $40.0 | $44.5 |

Source: U.S. EPA, 2011c.

### 10.4.2 Administrative Costs

As described above, these costs are calculated for the year of rule promulgation, 2012, as $833,000 at a three percent discount rate and $790,000 at a seven percent discount rate. As discussed in Section 1.2.3, the Control Authority could be the publicly owned treatment works (POTW), the state, or U.S. EPA Region. EPA estimated the annual recordkeeping costs and recurring costs (recordkeeping, inspections, reporting, and enforcement) for the following Control Authorities:

- 403.10(e) States: 5 Control Authorities;
- POTWs: 1,600 Control Authorities;[31]
- Approved Pretreatment States (minus the 403.10(e) States): 31 Control Authorities; and
- U.S. EPA Regions: 9 Control Authorities.[32]

EPA used a labor rate estimate of $55.18/hour[33] for these Control Authorities and an appropriate time estimate for each activity mentioned above (e.g., recordkeeping) (U.S. EPA,

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

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

2011e). See DCN DA00147. 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, 2011c and 2011d).

### 10.4.3 Total Social Cost

Table 10-17 summarizes the estimated total social cost for the proposed Dental Amalgam Rule, including both compliance costs and administrative costs. Costs are reported by the alternative number-of-chair distributions and for the three and seven percent discount rates.

**Table 10-17. Summary of Social Cost for Proposed Dental Amalgam Rule**

| Annualized Cost (Millions, $2010) as of 2012, 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 | $43.6 | $48.5 | $40.0 | $44.5 |
| Cost to permitting authorities | $0.9 | $0.9 | $0.8 | $0.8 |
| Total social cost | $44.5 | $49.4 | $40.8 | $45.2 |

## 10.5 REGULATORY FLEXIBILITY ACT ASSESSMENT

As part of the cost and economic impact assessment for the proposed Dental Amalgam Rule, EPA considered the potential impact on small entities in the dental office business. Of key concern in this assessment is whether the proposed Dental Amalgam 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 $7.0 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 *small* dental office firms are single establishment businesses, 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 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 in-scope dental offices *do not process dental amalgam,* and thus would be expected to incur no or limited costs under the proposed Dental Amalgam Rule.

[33] Metal products and machinery 150 POTW Study ($1999). EPA took the $1999 and using the Bureau of Employment Cost Index for State and Local Government Public Administration converted to $2010 (U.S. EPA, 2000).

Based on these adjustments, EPA estimated that approximately 126,800 dental offices are small businesses and that approximately 109,600 of these small business dental offices are in scope for the proposed rule and thus could incur costs under the rule. Because the number of small business dental offices that process amalgam is only 259 offices less than the total dental offices (109,862), 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 Section 10.3.1.1, which used one and three percent of revenue thresholds as impact measures. As described in that section, 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 10-18 summarizes the results for small entities from this analysis.

**Table 10-18. Cost-to-Revenue Impact Analysis for Small Entities**

| 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** | | | | | | | |
| 33 | 474 | 507 | 0.5% | 0 | 0 | 0 | 0.0% |
| **Including Baseline Set-Aside Offices in Analysis** | | | | | | | |
| 243 | 722 | 965 | 0.9% | 51 | 169 | 221 | 0.2% |

Results are the same for both the ADA National and Colorado distributions of chairs by office.
Percentages of affected offices are calculated as a fraction of total small business offices estimated to incur costs under the proposed Dental Amalgam Rule.
Source: U.S. EPA, 2011c.

As shown in Table 10-18, with the *baseline set-aside offices* excluded from the analysis, EPA estimates that 507 dental offices would incur costs exceeding one percent of revenue.[34] These offices represent 0.5 percent of the small business offices estimated to incur costs under the proposed Dental Amalgam Rule. EPA estimates that no small entities would incur costs exceeding three percent of revenue for the proposed rule.

With the *baseline set-aside offices* included in the analysis, EPA estimates that 965 dental offices would incur costs exceeding one percent of revenue. These offices represent 0.9 percent of small business offices estimated to incur costs under the proposed Dental Amalgam Rule. EPA estimates that 221 dental offices would incur costs exceeding three percent of revenue, representing 0.2 percent of small business offices estimated to incur costs under the proposed Dental Amalgam 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,

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

EPA estimates that the proposed Dental Amalgam Rule would not impose a significant impact on a substantial number of small entities (SISNOSE).

## 10.6 REFERENCES

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# SECTION 11
# POLLUTANT REDUCTION ESTIMATES

The proposed rule establishes a pretreatment standard that would require removal of at least 99.0 percent of total mercury from amalgam discharges and best management practices (BMPs). EPA's pollutant reduction methodology assumes dental offices would use the required BMPs in combination with 2008 ISO 11143 amalgam separators, the proposed technology basis, to comply with the proposed rule.

EPA does not have office-specific discharge data for the approximately 110,000 dental offices potentially subject to the proposed rule. Instead, EPA has modeled the discharges of mercury and other metals based on nationwide estimates of amalgam fillings placed (restorations) and removals and did not calculate the pollutant loadings and reductions on a per office basis. Rather, EPA calculated average mercury (and other pollutant) loadings by dividing the pollutant loadings from the total number of annual procedures by the total number of dentists performing these procedures.[35] 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 sections describe the methodology in more detail.

## 11.1 NATIONAL ESTIMATE OF ANNUAL POLLUTANT LOADINGS FROM DENTAL OFFICES

This section 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. 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. Each amalgam capsule contains 450 milligrams (mg) of mercury and, on average, dentists use 75 percent of the capsule for the filling. The 25 percent of mercury remaining in the capsule is discarded as gray bag waste. Therefore, approximately 340 mg of mercury (75 percent of the capsule) are used per filling. Further, 9 percent of those 340 mg (31 mg) is discharged to 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 tons of mercury nationwide[36] in their wastewaters from restorations (U.S. EPA, 2011). Table 11-1 presents how mercury waste is generated at dental offices during amalgam restorations.

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

[36] 71 million restorations times 31 mg per filling.

**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<br><br>*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<br><br>*2.4 tons per year from all procedures* |
| | | 110 mg (25% of total mercury) remains in capsule | | Discarded as gray bag waste |

Sources: U.S. EPA, 2011; 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. Based on this information, EPA estimates that approximately 97 million amalgam removals occur each year (U.S. EPA, 2011). An average of 300 mg mercury is removed from each filling (Vandeven and McGinnis, 2005). EPA assumed that 90 percent of the removed filling (270 mg mercury) becomes part of the dental office wastewater, and the other 10 percent is handled as dry waste and/or gray bagged. Thus, EPA estimated dental offices generate 29 tons of mercury in their wastewaters from amalgam filling removals each year[37] (U.S. EPA, 2011). 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<br><br>*97 million procedures per year* | 300 milligrams (mg) per removed filling | 270 mg (90% of total mercury) | Rinsed into wastewater drain<br><br>*29 tons per year from all procedures* |
| | | 30 mg (10% of total mercury) | Dry waste disposal/gray bag waste |

Sources: U.S. EPA, 2011; Vandeven and McGinnis, 2005.

Summing the total mercury loading from the annual number of restorations and filling removals, EPA estimated dental offices generate 31.4 tons of mercury annually as part of dental office wastewaters, see Table 11-3.

[37] 97 million amalgam filling removals times 270 mg per removal.

**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 | 97 million | 270 mg | 29 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** | | | **31.4 tons** | |

Sources: U.S. EPA, 2011a; Vandeven and McGinnis, 2005.

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

EPA estimated that within the 109,972 dental offices potentially subject to the proposed Dental Amalgam Rule, 13,102 offices do not place or remove amalgam and therefore do not generate amalgam wastewater (Section 10.1.2). Therefore, the remaining 96,870 offices collectively generate 31.4 tons of mercury in their wastewaters. This equates to 0.65 pounds per office. However, as explained earlier, these 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): 19,374 dental offices.
- 44,461 dental offices use amalgam separators (U.S. EPA, 2011).
- The remaining 33,035 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 52,000 dental offices without amalgam separators collectively discharge a total of 4.4 tons of mercury to POTWs per year. The approximately 44,000 dental offices with amalgam separators collectively discharge approximately 63 pounds 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 4.4 tons, out of a total of the 31.4 tons originally generated (U.S. EPA, 2011).

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 | 19,374 | 68% |
| Chair-Side Traps and Vacuum Filter Only | 33,035 | 78% |
| Amalgam Separator | 44,461 | 99.0% |
| **Total** | **96,870** | **--** |

Sources: U.S. EPA, 2011; 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 a small amount of zinc (Massachusetts Water Resources Authority, 2001). Using the mercury generation estimates in Section 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**

| Description | Pollutant in Dental Office Wastewater | Per Procedure | Annual Loading (Untreated) | Notes |
|---|---|---|---|---|
| Amalgam Restorations | Mercury | 31 milligrams (mg) | 2.4 tons (U.S.) | Estimate non-mercury metals entering wastewater based on ratio of amalgam composition: 49 percent mercury and 51 percent non-mercury metals. |
| | Non-Mercury Metals | 32 mg | 2.5 tons (U.S.) | |
| Amalgam Removals | Mercury | 270 mg | 29 tons (U.S.) | |
| | Non-Mercury Metals | 281 mg | 30 tons (U.S.) | |

Sources: U.S. EPA, 2011.

### 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 99.0 percent removal of all amalgam metals at offices with amalgam separators in place. Using the same methodology as described for mercury in Section 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 loading generated by amalgam removals as 30 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 4.6 tons, out of a total of 32.5 tons originally generated (U.S. EPA, 2011).

### 11.1.5 Total Annual Baseline Discharges to POTWs

After accounting for existing technologies at dental offices, EPA estimated dental offices collectively discharge 4.4 tons of mercury and 4.6 tons of additional metals to POTWs per year for a total discharge to POTWs of 9.0 tons annually.

## 11.2 National Estimate of Annual Pollutant Reductions to POTWs Associated with the Proposed Dental Amalgam Rule

EPA estimated that the 52,409 dental offices (19,374 dental offices with chair-side traps only and the 33,035 dental offices with chair-side traps and vacuum filters only) would install 2008 ISO 11143 certified amalgam separators with a removal efficiency of at least 99.0 percent as a result of the proposed Dental Amalgam Rule. 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, 2011). This would result in reduction of total mercury discharges to POTWs by 4.3 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 4.5 tons. Again, EPA assumes the dissolved metal content to be negligible.

Accordingly, the proposed Dental Amalgam Rule would annually reduce mercury discharges by 4.3 tons and other metal discharges by 4.5 tons for a total annual reduction to POTWs of 8.8 tons.

## 11.3 National Estimate of Annual Pollutant Reductions to Surface Waters Associated with the Proposed Dental Amalgam 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 to calculate POTW removals of each metal. As detailed above, at baseline and prior to implementation of the proposed rule, EPA estimated that, collectively, dental offices discharge 4.4 tons[38] of dental mercury annually to POTWs. Based on the 50 POTW Study, EPA estimates that POTWs remove 90 percent of the 4.4 tons mercury from the wastewater. Thus, POTWs collectively discharge 880 pounds of dental mercury to surface waters annually.

[38] 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).

Under the proposed Dental Amalgam Rule, over 98 percent of mercury solids currently discharged annually to POTWs will be removed by the installation of amalgam separators. The POTWs then further remove 90 percent of total mercury from the wastewater. This reduces the total amount of dental mercury discharged from POTWs nationwide to surface water to 14 pounds annually. In other words, discharges of mercury to waters of the United States are expected to be reduced by 860 pounds per year[39] as a result of the proposed rule.

Based on the 50 POTW Study (U.S. EPA, 1982), POTWs remove the following from wastewater prior to discharge:

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

At baseline, EPA estimates that dental offices discharge over 9,000 pounds of non-mercury amalgam metals to POTWs annually. After treatment at the POTW, POTWs collectively discharge 1,280 pounds of non-mercury amalgam metals to surface waters annually. Under the proposed Dental Amalgam Rule, the non-mercury amalgam metal discharges from POTWs to surface waters will be approximately 20 pounds, a reduction of 1,260 pounds. This results in the total reduction of amalgam metals (mercury and non-mercury) to waters of the United States by an estimated 2,120 pounds (U.S. EPA, 2011).

## 11.4 REFERENCES

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Vandeven, J., and S. McGinnis. 2005. An Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States. Water, Air, and Soil Pollution, 164:349-366. DCN DA00163.

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

# SECTION 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 proposed option to those for effluent limitation guidelines and standards (ELGs) for other industries. This definition includes the concepts discussed in this section.

## 12.1 TOTAL INCREMENTAL ANNUALIZED COMPLIANCE COSTS

The cost-effectiveness analysis uses the estimated total annual costs of complying with the proposed rule. As described in Section 10.3, 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. For this proposal, EPA adjusted the value using the Bureau of Economic Analysis GDP Implicit Price Deflators.[40] EPA calculates this adjustment factor as follows:

Adjustment factor = (1981$) ÷ (2010$) = **52.270** ÷ **110.992** = 0.47093

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

**Table 12-1. Annualized Compliance Costs (Million $)**

| Dental Office Distribution Data Source | Annualized Compliance Costs At Promulgation Year (million 2010$) | GDP Deflator to Convert 2010$ to 1981$ | Annualized Compliance Costs (million 1981$) |
|---|---|---|---|
| ADA Colorado Survey | $43.6 | 0.47 | $21 |
| ADA National Survey | $48.5 | | $23 |

Source: U.S. EPA, 2011a.

## 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.[41] EPA derives toxic weighting factors for each pollutant using chronic aquatic life criteria (or toxic effect levels) and human health criteria (or toxic effect levels) established for the consumption of fish. Table 12-2 lists the TWFs for the pollutants found in dental discharges.

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

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

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

| Pollutant | Toxic Weighting Factor |
|---|---|
| Total mercury | 117.12 |
| Silver | 16.47 |
| Tin | 0.30 |
| Copper | 0.63 |
| Zinc | 0.05 |

## 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 proposed rule for each pollutant identified in dental amalgam. Because this proposed rule is for indirect discharges, this estimate appropriately accounts for discharge reductions that occur at the publicly owned treatment works (POTW). See Section 10 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 proposed rule. Table 12-3 presents the estimate of individual and total annual incremental pound-equivalent removals from surface waters for the proposed rule.

**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 | 863 | 117.12 | 101,048 |
| Silver | 722 | 16.47 | 11,896 |
| Tin | 331 | 0.30 | 100 |
| Copper | 167 | 0.63 | 106 |
| Zinc | 37 | 0.05 | 2 |
| Total | | | 113,152 |

Source: U.S. EPA, 2011c.

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 proposed rule is \$181-\$201/lb-eq (\$1981).

**Table 12-4. PSES Cost-Effectiveness Analysis**

| Dental Office Distribution Data Source | Pre-Tax Total Annualized Costs ($1981) | Removals (lbs-eq) | Average Cost-Effectiveness ($1981) |
|---|---|---|---|
| ADA National Survey | $23,000,000 | 113,152 | $201 |
| ADA Colorado Survey | $21,000,000 | 113,152 | $181 |

Source: U.S. EPA, 2011a.

EPA presents cost effectiveness in 1981 dollars as a reporting convention. This allows EPA to compare the cost-effectiveness of various ELGs. EPA calculates cost-effectiveness as the ratio of pre-tax annualized costs of an option to the annual pounds-equivalent removed by that option. For the proposed Dental Amalgam Rule, it is expressed as the average cost-effectiveness for the option. Average cost-effectiveness can be thought of as the increment between no regulation and the selected option for any given rule. The technology basis for PSES in this proposed rule has a cost-effectiveness ratio of $181 to $201 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.

## 12.5 References

U.S. EPA. 2011a. Economic Analysis for the Dental Amalgam Rule. MS Excel™ file. Office of Water. Washington, DC. Document Control Number (DCN) DA00145.

U.S. EPA. 2011b. *Technical Support Document for the 2010 Effluent Guidelines Program Plan*. EPA-820-R-10-021. Office of Water. Washington, DC. DCN DA00225.

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# SECTION 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 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 Section 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, 2011a). Studies indicate that dental offices are a primary source of mercury entering POTWs. Through treatment, POTWs remove approximately 90 percent of dental mercury from wastewater and transfer it to sewage sludge. The 10 percent of dental mercury not removed by POTW treatment is discharged to surface water.

### 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 sulfur-reducing bacteria. Methylmercury is easily absorbed into muscle and fat tissues, but it is not readily excreted due to its low water solubility. Methylmercury thus has high potential to become increasingly concentrated up through the aquatic food chains, as larger fish eat smaller fish. This accumulation can be profound, with biomagnifications of 100,000 times from algae to top predators having been documented (Chin, et al., 2000).

The neurological effects of eating fish contaminated with methylmercury are well documented (WI DNR, 1997). Developmental effects to fetuses, infants, children, and women of childbearing age are of special concern. Neurological effects from predation of methylmercury contaminated fish have been documented 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, methylmercury in fish can also come from existing background concentrations of mercury, which may consist of mercury from natural sources, mercury re-emitted from the oceans or soils, or mercury deposited in the United States from sources in other countries. Current scientific understanding of mercury's environmental fate and transport does not allow quantification of how much of the methylmercury in fish consumed by the U.S. population is contributed by U.S. emissions, nor how much derives from natural mercury sources, or for that matter, from dental discharges.

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 at 40 CFR 503, *Standards for Use and Disposal of Sewage Sludge*, 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 4,800 pounds of dental mercury enters the environment as 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 facilities such as sewage sludge mono-fills or municipal landfills (U.S. EPA, 1999). EPA estimates that approximately 1,400 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.

The remaining 22 percent, or 2.5 billion pounds, of sewage sludge generated annually by POTWs is incinerated (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). 40 CFR 503 limits the quantity of mercury and other toxic metals allowed per unit amount of sewage sludge prior to incineration. Concentrations of mercury emitted from sewage sludge incinerators must meet the National Emissions Standards for Hazardous Air Pollutants requirements in subpart E of 40 CFR 61.

### 13.3.3 Environmental Benefits of the Proposed Dental Amalgam Rule

EPA did not perform an environmental benefits analysis of the proposed rule due to insufficient data about the aquatic fate and transport of dental mercury discharged by POTWs.

However, EPA was able to assess the qualitative environmental benefits based on existing information. Studies have shown that decreased point source discharges of mercury to surface water result in lower methylmercury concentrations in fish. Moreover, several studies have quantified economic benefits from improved human health and ecological conditions resulting from lower fish concentrations of methylmercury (U.S. EPA, 2011a). The proposed requirement for installation of amalgam separators with 99.0 percent mercury removal efficiency will produce human health and ecological benefits by reducing the estimated annual nationwide POTW discharges of dental mercury to surface waters from 880 pounds to 14 pounds (U.S. EPA, 2011b). In addition, the decreased discharges to POTWs will result in a decrease of mercury in biosolids.

## 13.4 References

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# SECTION 14
# NON-WATER-QUALITY IMPACTS

Eliminating or reducing one form of pollution may cause other environmental problems. Sections 304(b) and 306 of the Clean Water Act require EPA to consider non-water-quality environmental impacts (including energy requirements) associated with effluent limitation guidelines and standards (ELGs). To comply with these requirements, EPA considered the potential impact of amalgam separators and best management practices (BMPs) on energy consumption, air pollution, and solid waste generation. EPA anticipates that the proposed Dental Amalgam Rule will produce minimal non-water-quality impacts. The Administrator has determined that these very minimal impacts are acceptable.

## 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 proposed rule. As described in Section 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 essentially all of the excess amalgam from the wastewater. Most separators rely on gravity or the suction of the existing vacuum system to operate and do not require an additional electrical power source. As a result, EPA expects operation of an amalgam separator would pose negligible additional energy requirements on the existing vacuum pump.

While the vendor data used to support the proposed rule did not include incremental energy requirements for an amalgam separator, EPA is aware that some units described in the literature may require small pumps to remove settled effluent from the separator (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. Based on this evaluation, EPA concluded there will be no significant non-water-quality impacts associated with the energy requirements for the proposed 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 carried by wastewater to the publicly owned treatment works (POTW), where approximately 90 percent is removed from the wastewater into the POTW sludge; the sludge may be land applied, disposed of in landfills or mono-fills, or incinerated. The proposed rule is expected to increase the use of amalgam separators nationwide—EPA expects over 50,000 dental offices to install amalgam separators to comply with the proposed rule (see Table 10-2). Currently, just under 45,000 dental offices have separators installed (see Table 10-2). EPA expects the collected amalgam that is no longer discharged to the POTW will be recycled via the spent separator canisters. The operation and maintenance requirements associated with the amalgam separator compliance option will promote recycling as the primary means of amalgam waste management. EPA expects the proposed rule will not create additional solid waste, but will instead change how dental amalgam is handled. Nationally, EPA expects less dental amalgam will partition to the POTW wastewater sludge, leading to reductions in the amount of mercury currently land-applied, landfilled, or released to the air during incineration. Instead, it will be collected in separator canisters and recycled. Based on this evaluation of solid waste generation, EPA concluded that there will be a reduction in non-water-quality impacts associated with solid waste generation as a result of the proposed 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 proposed rule will not pose any increases in air pollution. EPA concluded that there will be no significant non-water-quality impacts associated with air emissions as a result of the proposed Dental Amalgam Rule.

## 14.4 REFERENCES

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# SECTION 15
# IMPLEMENTATION

This section provides guidance to Control Authorities, such as publicly owned treatment works (POTWs) in implementing Effluent Limitation Guidelines and Standards (ELGs) for the Dental Category.

## 15.1 IMPLEMENTATION DEADLINE FOR EXISTING SOURCES

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

## 15.2 IMPLEMENTATION DEADLINE FOR NEW SOURCES

For new sources, the compliance deadline is governed by EPA's regulation at 40 CFR 403.6(b), which provides that "New Sources shall install and have in operating condition, and shall 'start-up' all pollution control equipment required to meet applicable Pretreatment Standards before beginning to Discharge. Within the shortest feasible time (not to exceed 90 days), new Sources must meet all applicable Pretreatment Standards." Table 15-1 presents the implementation deadline for existing and new sources of dental amalgam discharges.

**Table 15-1. Compliance Time for Dental Offices Potentially Subject to the Proposed Rule**

| Dental Office | Requirement | Deadline |
|---|---|---|
| Existing Office that Dischargers to the Sewer | Comply with PSES | Three years after the effective date of any final rule. |
| New Office that Discharges to the Sewer | Comply with PSNS | When discharging begins. |

## 15.3 REPORTING REQUIREMENTS

The following describes the steps a dental office would take to comply with the reporting requirements associated with the proposed rule:

1. A dental office (or facility) should determine if any of its operations are potentially subject to the proposed rule.

   i. Does the office discharge to a sewer or directly to a POTW? If not, the office in not potentially subject to the proposed rule and does not have any obligations.

   ii. Does the office exclusively practice one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics? If yes, the office is not potentially subject to the dental amalgam proposed rule.

2. If an office or facility is subject to the proposed rule, it should determine whether it places or removes amalgam. If it does neither (except in limited emergency circumstances), it would certify that to the Control Authority.

   i. If an office or facility is subject to the proposed rule and places or removes amalgam, it will need to comply with the general reporting requirements, which include submission of two one-time reports: a 90-day compliance report and a baseline monitoring report. The latter must be submitted within 180 days of the effective date of any final rule. The office or facility will also have to submit an annual certification.

# SECTION 16
# UPDATES TO GENERAL PRETREATMENT STANDARDS
# (40 CFR 403)

In addition to the pretreatment standards for dental offices, EPA is proposing to amend selected parts of the General Pretreatment Regulations to simplify oversight requirements for the approximately 110,000 dental offices subject to this rule. When EPA promulgates categorical industrial pretreatment standards, as defined in 40 CFR 403, affected dischargers are referred to as Categorical Industrial Users (CIUs). The number of dental offices subject to the proposed Dental Amalgam Rule is approximately 10 times the current number of CIUs. EPA recognized that regulatory oversight of this increased number of CIUs would need to be very different from regulating the current number of CIUs. Using the existing regulatory framework to enforce categorical pretreatment regulation on this industry would require an increase in available local, state, and federal resources; and EPA does not expect such efforts to result in greater environmental benefit. EPA is focusing on providing technical means to reduce administrative burden to dentists and Control Authorities, while still providing a clear understanding of who is affected and what they are expected to do, and achieving the projected pollutant reductions.

## 16.1 PROPOSED CHANGES TO THE GENERAL PRETREATMENT STANDARDS

EPA is proposing a new classification of CIU specifically tailored to the Dental Office Effluent Limitation Guidelines and Standards rule: "Dental Industrial User" (DIU). EPA is proposing that such users not be subject to the oversight requirements for Significant Industrial Users, or SIUs (i.e., control mechanism issuance requirement, annual inspection, and sampling requirements). Rather, EPA is proposing to allow Control Authorities to focus their oversight efforts on those dental offices that fail to meet the compliance requirements of the DIU.

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

If the dental office does not meet the requirements to be classified as a DIU, under the proposed rule, the Control Authority would be required to classify the dental amalgam discharger as an SIU as defined in 40 CFR 403.3(v). As an SIU, the Control Authority would be required to conduct the oversight duties applicable to SIUs as described in 40 CFR 403.8(f).

EPA notes that the proposed changes to 40 CFR 403 to create the DIU classification are changes that the Control Authority may adopt at its discretion. The changes to Part 403 provide program flexibility and are not required to be incorporated into the state or POTW's Pretreatment Program. However, for Control Authorities to designate dental offices as DIUs, the state and

POTW Pretreatment Program would need to incorporate the proposed changes into their legal authority under 40 CFR 403.8(f)(l).

## 16.2 RESPONSIBILITIES OF THE CONTROL AUTHORITIES

As described in Section 1.2.3, the Control Authority (either the POTW or state/EPA Region) is responsible for permitting, sampling, and inspecting industrial users that discharge to POTWs. The proposed rule would require that a Control Authority evaluate, at least once per year, whether an industrial user previously determined to be a DIU still meets the criteria for treatment as a DIU under 40 CFR 441.60. EPA anticipates that this evaluation will primarily involve the Control Authority's verification that the certification has been submitted by the dental office to document their continued eligibility for DIU status.

### 16.2.1 Noncompliance

In accordance with 40 CFR 403.8(f)(2)(viii)(F), a dental amalgam discharger that is classified as a DIU would be in significant noncompliance if it fails to provide any required report within 45 days of the due date, or if the Control Authority inspects the office and finds the office is not in compliance with 40 CFR 441.60. Upon discovery that a dental practice is not in compliance with regulations at 40 CFR 441.60 (either reporting requirements, Part 403, or Part 441 PSES/PSNS requirements), the Control Authority must initiate enforcement in accordance with its approved pretreatment program to return the dental amalgam discharger into compliance. To continue to treat the dental office as a DIU, the Control Authority would need to verify and find, through an inspection, that the dental amalgam discharger has returned to full compliance with the criteria in Part 441.60. If, within 90 days, the Control Authority inspects, verifies, and finds that the dental amalgam discharger has returned to full compliance with Part 441.60, then the dental amalgam discharger would remain a DIU. The 90-day compliance deadline is consistent with other portions of 40 CFR 403 (e.g., significant noncompliance, compliance report deadlines, 90-day report after effective dates of categorical standards), and provides both the dental amalgam discharger and Control Authority with an incentive to provide a timely return to compliance. If the dental amalgam discharger has not returned to compliance within 90 days of the initial noncompliance, the Control Authority could no longer treat the dental amalgam discharger as a DIU, and the dental amalgam discharger would become an SIU. Control Authorities are required to oversee SIUs, which includes inspecting and sampling each SIU annually, reviewing the need for a slug control plan, and issuing a permit or equivalent control mechanism with a duration not to exceed five years (40 CFR 403.8(f)1)(iii) and (2)(v) and 403.10(f)(2)(i)).

### 16.2.2 Classification of Dental Offices as Non-Significant Categorical Industrial Users (NSCIU)

EPA is not proposing to prohibit a Control Authority from finding that a dental office or other facility may qualify as an NSCIU on an individual basis. State Approval Authorities and POTW Control Authorities with the legal authority to implement the NSCIU classification may find that one or more of their Dental Office CIUs may qualify as an NSCIU. However, since its promulgation in 2005, many state Approval Authorities and POTW Control Authorities have not adopted regulations to implement the NSCIU classification. EPA believes that the DIU classification, tailored for this single categorical pretreatment standard, while comparable to the

NSCIU classification, would be preferable because it would significantly reduce the Control Authority's burden in complying with the oversight requirements that would otherwise apply.

# SECTION 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 limitation 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.

**CESQG –** Conditionally Exempt Small Quantity Generators.

**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.

**DIU –** Dental Industrial User. New classification of CIU specifically tailored to the National Categorical Pretreatment Standards for the Dental Category.

**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.

**NSCIU** – Non-Significant Categorical Industrial User.

**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.

**Wastewater –** For this document, water emanating from dental facility.