

**INFORMATION COLLECTION REQUEST
SUPPORTING STATEMENT**

**EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS
FOR THE DENTAL CATEGORY
PROPOSED RULE**

**U.S. Environmental Protection Agency
Office of Water
Office of Science and Technology**

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PART A OF THE SUPPORTING STATEMENT

1. Identification of the Information Collection

a. Title of the Information Collection

Effluent Limitations Guidelines and Standards (ELGs) for the Dental Category; Proposed Rule (40 CFR Part 441). EPA ICR No. 2514.01. OMB No. 2040-NEW.

b. Short Characterization/Abstract

This Information Collection Request (ICR) seeks approval of the information requirements in the Proposed Rule for the Effluent Guidelines and Standards for the Dental Category. EPA is proposing standards under the Clean Water Act (CWA) for discharges of pollutants into publicly owned treatment works (POTWs) from certain existing and new dental practices that involve the discharge of dental amalgam. Mercury is discharged in the form of dental amalgam when dentists remove old amalgam fillings from cavities, and from excess amalgam removed when a dentist places a new filling.

The proposed rule would require all affected dentists to control mercury discharges to POTWs by reducing their discharge of dental amalgam to a level achievable through the use of the best available technology (amalgam separators) and the use of Best Management Practices.

EPA is also proposing to amend selected parts of the General Pretreatment Regulations (40 CFR Part 403) to streamline oversight requirements for the dental sector and reduce the reporting burden for dental offices.

2. Need for and Use of the Collection

a. Need/Authority for the Collection

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

b. Practical Utility/Users of the Data

The users of the data would be dental offices and their Control Authorities. By establishing categorical pretreatment standards for the dental category in 40 CFR Part 441, dental dischargers to POTWs would become subject to certain reporting requirements in 40 CFR Part 403. These include a requirement to submit a baseline monitoring report, 90-day compliance report and on-going monitoring and reporting requirements including results of discharge sampling. Under the proposed rule, a dental discharger is given the option of complying with reduced monitoring and reporting requirements in 40 CFR § 441.60, which are tailored for dental dischargers, in lieu of the otherwise applicable monitoring and reporting requirements in 40 CFR

part 403. Dental offices electing to comply with the proposed reporting requirements would need to certify annually that they 1) operate and maintain a dental amalgam separator certified to the ISO 11143 standard and 2) are complying with the best management practices defined in the proposed rule.

3. Non-Duplication, Consultations, and Other Collection Criteria

a. Non-Duplication

The rule does not duplicate other information requirements. Because dental dischargers to POTWs are not currently subject to reporting requirements for categorical dischargers, they are not currently required to submit the reports/certifications. There are no public sources available from which a control authority would be able to obtain this information.

b. Public Notice Required Prior to ICR Submission to OMB

A summary of the ICR for the rule is included in the Effluent Limitation Guidelines and Standards for the Dental Category Federal Register Notice. The values provided in the Federal Register Notice differ slightly from the numbers provided in this document. Specifically, EPA updated the values for Control Authorities.

c. Consultations

EPA met with stakeholders during the development of the proposed rule. Participants included the American Dental Association (ADA), and the National Association of Clean Water Agencies (NACWA), and the Environmental Council of the States. Stakeholders provided data on the characteristics of the dental industry, pollutant discharge characteristics, technologies and best management practices to reduce pollutant discharges, existing programs to reduce pollutants in dental discharges including reporting and monitoring requirements, and, and related regulatory issues. EPA also consulted with the Department of Defense, environmental groups, and dental amalgam separator manufacturers.

d. Effects of Less Frequent Collection

Dental offices are not currently required to report the characteristics of their discharges to Control Authorities. Beyond the initial reporting requirements that would be required in 40 CFR Part 403, the proposed rule would require dental offices to submit annual certifications of compliance. Data submission less frequent than annually would prevent the permitting authorities from carrying out their duties to enforce the requirements of the proposed rule.

e. General Guidelines

The information collection requirements of the rule are in accordance with the Paperwork Reduction Act guidelines in 5 CFR 1320.5(d)(2).

f. Confidentiality

Reports submitted to the Control Authority may contain confidential business information. However, EPA does not consider the specific information being requested by the rule to be typical of confidential business or personal information. If a respondent does consider this information to be of a confidential nature, the respondent may request that such information be treated as such. All confidential data will be handled in accordance with 40 CFR 122.7, 40 CFR Part 2, and EPA's Security Manual Part III, Chapter 9, dated August 9, 1976.

g. Sensitive Questions

The rule does not require respondents to divulge information of a sensitive nature, such as private or personal information.

4. The Respondents and the Information Requested

a. Respondent NAICS Codes

Dental Offices: The respondents affected by this information collection request are dental dischargers. The North American Industry Classification System (NAICS) identification number applicable to respondents is: 621210: Offices of Dentists. The U.S. Census Bureau describes this U.S. industry as 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 HMO medical centers. They can provide either comprehensive preventive, cosmetic, or emergency care, or specialize in a single field of dentistry. Dentistry may also be performed at larger institutional dental service facilities (e.g., clinics or dental schools). EPA is not proposing to include wastewater discharges from dental facilities where the practice of dentistry consists exclusively of one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics.

Control authorities: Control authorities have regulatory oversight for pollutant discharges to POTWs. The "Control Authority" refers to the POTW if the POTW has an approved pretreatment program, or the Approval Authority if it has not been approved, which may be the State or EPA. By establishing categorical pretreatment standards for the dental category, control authorities would be subject to certain additional oversight requirements in 40 CFR Part 403. Because of the large number of dental offices, EPA recognizes that the current regulatory framework in 40 CFR Part 403 would need to be adjusted for the effective implementation and enforcement of these pretreatment requirements on the dental industry. As such, EPA is also proposing changes to 40 CFR Part 403 to streamline oversight requirements for control authorities.

b. Information Requested

i. Data Items, Including Record Keeping Requirements

The proposed rule would require all affected dentists to control mercury discharges to POTWs by reducing their discharge of dental amalgam to a level achievable through the use of the best available technology and the use of Best Management Practices. In order to simplify compliance with, and enforcement of the numeric reduction requirements and to reduce costs, the proposed rule would allow dental offices to demonstrate compliance by certifying annually that they have installed and are operating and maintaining compliant amalgam separators and performing the specified best management practices. Similarly, the proposed rule would simplify the information that dental offices would be required to submit as required in 40 CFR Part 403 (including eliminating discharge monitoring) from the one time initial reporting requirements (i.e., baseline monitoring report and 90 day compliance report). The proposed rule would exempt dental dischargers that do not place or remove amalgam following a one-time certification to that effect.

ii. Respondent Activities

The dental office would complete a baseline monitoring report, a one-time compliance report and an annual compliance certification. Dental offices that do not place or remove amalgam would only complete a one-time certification. The proposal would require that a Control Authority evaluate, at least once per year, whether a dental discharger meets the criteria for reduced oversight requirements. EPA anticipates that this evaluation will primarily involve the Control Authority's verification that the required certifications have been submitted by the dental office documenting compliance

5. The Information Collected – Agency Activities, Collection Methodology, and Information Management

a. Agency Activities

EPA is responsible for overseeing the implementation of the rule. As explained above, implementation of reporting requirements would rely extensively on POTWs (if the POTW has an approved pretreatment program), or the Approval Authority if it has not been approved, which may be the State or EPA. Where the POTW does not have an approved pretreatment program and EPA is the Approval Authority, EPA performs the same activities as those outlined for Control Authorities in Section 4.

b. Collection Methodology and Management

A dental discharger would submit its annual report in a manner specified by the Control Authority. The proposal would require that a Control Authority evaluate, initially, and at least once per year, whether the dentist meets the criteria for reduced oversight. EPA anticipates that this evaluation will primarily involve the Control Authority's verification that the certification has been submitted by the dental office.

c. Small Entity Flexibility

The vast majority of the dental industry are small businesses as defined by the Small Business Administration. As described above, the proposed rule would enable these small businesses to minimize compliance reporting requirements.

d. Collection Schedule

As explained in Section 4.b.i, dental offices would be required to submit two one-time reports: the Baseline report would be due 180 days after the effective date of the rule and the 90 Day Compliance Report would be due within 90 days of the final compliance date of the rule. Periodic Monitoring Reports would be due once a year or as directed by the Control Authority. Those dental offices that do not place or remove amalgam would submit a one-time certification in lieu of any other reporting requirements.

6. Estimating the Burden and Cost of the Collection

a. Estimating Respondent Burden

Dentists: EPA assumed all affected dental offices would elect to comply with today's proposal through the proposed alternative in 40 CFR Part 441 rather than the otherwise applicable requirements for categorical dischargers in currently specified in 40 CFR Part 403. EPA estimates 109,972 dental offices would be subject to today's proposed rule. As explained above, dental offices would complete a one-time baseline monitoring report, a one-time compliance report and an annual compliance certification. EPA estimates that the completion of each of these reports would take 76 minutes, 51 minutes, and 49 minutes, respectively. Therefore, dental offices would require approximately 2 hours of labor associated with one time reporting and approximately one hour per year associated with the annual reporting requirements in this ICR. Dental offices that do not place or remove amalgam would only complete a one-time certification and EPA estimates this would take the same amount of time as the baseline monitoring report (76 minutes). As explained previously, EPA notes this is a reduction in burden that dental offices would otherwise experience under the existing reporting requirements that would apply in 40 CFR Part 403.

For those dental offices that do not place or remove amalgam, EPA estimated a total one-time labor of 16,600 hours. For the remainder, EPA estimates total one-time labor hours 205,000 and, thereafter, annual total labor hours of 79,100. See Table 1. Also see DCN DA000146.

Control Authorities: The costs to Control Authorities for review of the reports required by the proposed rule are significantly reduced from the existing regulatory scheme. As explained above, the current regulations (40 CFR Part 403) would require certain minimum oversight of dental dischargers by Control Authorities. The required oversight includes, but is not limited to, receipt and analysis of reports and other notices submitted by dischargers, annual inspection and effluent sampling, and permit issuance (or its equivalent). The proposal would change such requirements for oversight of dental dischargers in 40 CFR Part 403. The proposal would require

that a Control Authority evaluate, at least once per year, whether a dental discharger meets the criteria for reduced oversight requirements. EPA anticipates that this evaluation will primarily involve the Control Authority's verification that the required certifications have been submitted by the dental office documenting compliance. A Control Authority would only be required to perform the more detailed oversight requirements in the existing regulatory scheme in the event that a dental discharger, following notification and a reasonable amount of time to demonstrate compliance, failed to comply with the proposed regulation.

As described above, the entity serving the role as the Control Authority varies. For purposes of this burden estimate, EPA estimates 36 States and 1,600 POTWs may serve as Control Authorities for Dental Dischargers. For purposes of this ICR, EPA assumed almost all Control Authorities would elect to comply with the proposed reduced oversight requirements for dental dischargers. Therefore, EPA assumed 1% of Control Authorities would need to conduct inspections/enforcement activities.

EPA estimated one-time recordkeeping burden associated with the one-time reports as well as annual recordkeeping and reporting burden. EPA also included burden for 1% of Control Authorities to perform inspection/enforcement activities. EPA estimates total one-time total labor of 1,064 hours and recurring total annual labor of 15,159 hours. For details on how EPA estimated each of the components, see DCN DA000147. Also see Table 2.

b. Estimating Respondent Costs

i. Estimating Labor Costs

Dentists: EPA estimated dental office labor costs for the specific activities related to the proposed reporting requirements of the rule. EPA based the labor costs for the proposed reporting requirements on average labor costs as reported for dental assistants from the Bureau of Labor Statistics in May, 2011 (\$16.41/hour). EPA used the estimated hours required to respond to the requirements of the proposed rule and multiplied these costs by this labor rate. For those dental offices that do not place or remove amalgam, EPA estimated a one-time labor cost of \$272,000. For the remainder, EPA estimates total one-time labor costs of \$3,640,000 and, thereafter, annual total labor costs of \$1,300,000. See Table 1.

Control Authorities: EPA estimated Control Authority labor costs for the specific activities related to oversight requirements. EPA based the labor costs for Control Authorities on average labor costs as reported for Control Authorities in Effluent Limitation Guidelines and Standards for the Metal Products and Machinery Category. These costs reflect \$1999. EPA took the \$1999 labor rate (\$/hour) and using the Employment Cost Index for State and Local Government Public Administration converted to \$2010 (\$55.18/hour). EPA used the estimated hours required to respond to the requirements of the proposed rule and multiplied these costs by this labor rate. EPA estimated that control authorities will incur total one-time recordkeeping costs of \$58,700 and total recurring annual administrative costs of \$836,400. See Table 2.

Table 1. Estimated Dental Office Burden and Labor Costs for One-Time Reports and Annual Certification					
Activity	Estimated Burden Hours Per Office	Estimated Cost Burden Per Office^a	Number of Dental Offices Conducting Activity	Total Hours	Total Cost
One Time Reports					
Certify No Use of Amalgam	1.267	\$21.5	13,102	16,600	\$272,000
Baseline Monitoring Report	1.267	\$21.5	96,870	123, 000	\$2,010,000
90 Day Compliance Report	0.85	\$13.9	96,870	82,300	\$1,350,000
Total for One Time Reporting-Year 1				222,000	\$3,640,000
Annual Certification- Year 1	0.82	\$13.4	96,870	79,100	\$1,300,000
Annual Certification- Year 2	0.82	\$13.4	96,870	79,100	\$1,300,000
Annual Certification- Year 3	0.82	\$13.4	96,870	79,100	\$1,300,000
Annual Average				153,000	\$2,510,000

a – Labor rate of \$16.41 per hour for a dental assistant based from Bureau of Labor Statistics (May, 2011).

Table 2: Estimated Control Authority Burden and Labor Costs for One-Time Reports and Annual Certification		
Activity	Total Estimated Burden Hours	Total Estimated Cost Burden
Total One-Time Burden for Control Authority	1,064	\$58,700
Total Annual Burden for Control Authority	15,159	\$836,400
Total Costs in Year 1	16,223 ¹	\$895,200
Total Costs in Year 2	15,159	\$836,400
Total Costs in Year 3	15,159	\$836,400
Total Average Annual Cost over 3-year period	15,514	\$856,000 ¹
May not add due to rounding		

¹ This is the sum of the total on-time burden and the burden for the first year of the annual certification.

ii. Estimating Capital and Operations and Maintenance (O&M) Costs

Because EPA is not requiring respondents (dental offices or Control Authorities) to purchase any nonexpendable goods, including equipment or machinery, to perform reporting, the Agency does not expect capital costs to result from the reporting requirements. Operation and maintenance costs include only printing and postage for each of the one-time reports and the annual certification statements that would be submitted by dental offices. Because the reports/certifications will be a page or two and because dental offices print routinely, EPA assumed this cost per dental office would be negligible. EPA estimated postage costs applying the current United States Post Office first class postage rate of \$0.49 for each one-time report/certification. EPA applied these rates to the respondents in Table 1 for a total one-time postage cost of \$101,000 and a total annual postage cost for this ICR of \$47,500. The total average O&M cost is \$81,000.

iii. Annualizing Capital Costs

There are no capital costs associated with any of the reporting, as described above.

c. Estimating Agency Burden and Costs

As explained above, where a POTW does not have an approved pretreatment program, EPA (Regions) may serve as the Approval Authority. Where EPA is the Approval Authority, EPA will incur costs and burdens similar to those incurred Control Authorities described above. EPA estimates total one-time total labor of 200 hours and recurring total annual labor of 2,200 hours. The total annual average labor hours is 2300 hours. In a similar manner, EPA estimated that it would incur total one-time recordkeeping costs of \$12,000 and total recurring annual administrative costs of \$124,000. The total annual average is \$128,000. For details on how EPA estimated Agency burden and costs, see DCN 000147.

d. Estimating the Respondent Universe and Total Burden Costs

Dentists: The estimated dental office universe for any reporting is for compliance determination reporting is approximately 110,000 dental offices. Some offices would be required to provide one-time reports only while others would be required to provide one time reports and annual certification. EPA estimates the total one-time labor hours associated with this ICR to dental offices to be 222,000 and total annual labor hours to be 79,100 hours for a total annual average of 153,000 hours. Similarly, EPA estimates the total one-time labor costs to dental offices to be \$3,640,000 and total annual labor costs to be \$1,300,000 for a total annual average of \$2,510,000. See Table 1. In addition, EPA estimated respondents would incur O&M in the form of postage. The total annual average postage is \$81,000.

Control Authorities: For purposes of this ICR, EPA estimated the non-EPA Control Authority universe to be 36 States and 1,600 POTWs. EPA estimates total one-time total labor of 1,100 hours and recurring total annual labor of 15,200 hours for a total annual average of 15,500 hours. Similarly, EPA estimates that control authorities will incur total one-time recordkeeping costs of \$58,700 and total recurring annual administrative costs of \$836,000 for a total annual average of \$856,000. See Table 2.

e. Bottom Line Burden Hours and Cost Tables

i. Respondent and Agency Burden Hours and Costs

Table 3. Summary of Total Burden and Costs for Respondents (Dentists) and Control Authorities

	Respondents	Total Annual Average Burden (Hours)	Total Annual Average Costs
Dental Offices	110,000	153,000	\$2,510,000
Control Authority (POTWs and States)	1636	15,514	\$856,000
TOTAL		168,500	\$3,370,000
May not add due to rounding			

Table 4. Summary of Total Burden and Costs for Agency (EPA)

	Respondents	Total Annual Average Burden (Hours)	Total Annual Average Costs
EPA	9	2,300	\$128,000
TOTAL		2,300	\$128,000

ii. Variations in the Annual Bottom Line

The burden to Control Authorities would increase for dental dischargers that do not submit the required reports in a timely manner.

f. Reasons for Change in Burden

Not applicable, because this request does not renew or modify an existing ICR.

g. Burden Statement

The information collection requirements in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An Information Collection Request (ICR) document has been prepared by EPA and has been assigned EPA 2514. The information collection requirements are not enforceable until OMB approves them. EPA estimates it would take a total annual average of 153,000 hours and \$2.5 million for affected dental offices to collect and report the information required for certification in the proposed rule. This estimate includes effort associated with completing the baseline monitoring report, a one-time compliance report and an annual compliance certification for each year of this three year

ICR. This estimate is based on average labor rates from the Bureau of Labor Statistics for the dental office personnel involved in collecting and reporting the information required. EPA estimates it would take a total annual average of 15,514 hours and \$856,000 for control authorities to review the information submitted by dentists that certify they meet the requirements in the proposed rule. EPA estimates that there would be no start-up or capital costs associated with the information described above. Burden is defined at 5 CFR 1320(b).

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