

**INFORMATION COLLECTION REQUEST
SUPPORTING STATEMENT**

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

EPA ICR NUMBER 2514.03

**U.S. Environmental Protection Agency
Office of Water
Office of Wastewater Management**

June 1, 2020

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Terms of Clearance:

None.

A. Justification.

- 1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.**

On 6/4/17, EPA promulgated a regulation under the Clean Water Act (CWA) to reduce discharges of mercury from dental offices into municipal sewage treatment plants known as publicly owned treatment works (POTWs). 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 Dental Office Category (40 CFR Part 441) regulation require affected dental offices 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 or best available demonstrated control technology. Specifically, dental offices will have to use amalgam separators and the use of two best management practices (BMPs) – a prohibition on the discharge of waste (or “scrap”) amalgam to POTWs and a prohibition of the use of vacuum line cleaners that are oxidizing or acidic and that have a pH higher than 8 or lower than 6.

Dental dischargers are required to certify in a One-Time Compliance Report that they 1) do not remove amalgam except in limited emergency or unplanned, unanticipated circumstances and do not use amalgam; or 2) that they are complying with the standards specified in the regulation. They also must maintain on-site all records of compliance, as described in the regulation, and make them available for inspection, upon request.

This ICR is seeking to continue to collect the data elements required in the regulation, as described in § 441.50(a). EPA has created a form to serve as a sample one-time compliance report that Control Authorities may use for the collection of the information required in the regulation. This ICR defines the minimum that needs to be collected, but it does not specify the full breadth of information or the format in which it is collected. Control Authorities (which may be POTWs, states or EPA and as defined at 40 CFR 441.20) may use their own form, provided it meets the requirements of the regulation. To summarize the information requested in the compliance form, the following section headers are highlighted below with their corresponding regulation requirement:

- **General Information:** § 441.50(a)(3)(ii)(A) and § 441.50(a)(3)(ii)(B)
- **Applicability:** § 441.50(a)(3)(i), § 441.50(a)(4), and § 441.10
- **Section A, Description of Facility:** § 441.50(a)(3)(ii)(C)

- **Section B, Description of Amalgam Separator or Equivalent Device:** § 441.50(a)(3)(ii)(C)
- **Section C, Design, Operation and Maintenance of Amalgam Separator/Equivalent Device:** § 441.50(a)(3)(ii)(D) and § 441.50(a)(3)(ii)(F)
- **Section D, Best Management Practices (BMP) Certifications:** § 441.50(a)(3)(ii)(E)
- **Section E, Certification Statement:** § 441.50(a)(2)
- **Retention Period:** § 441.50(a)(5)

Control Authorities are responsible for oversight of the pretreatment standards. Oversight will be accomplished largely through the review of reports submitted by the dental offices.

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

- 2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

This is a collection renewal.

Control Authorities (including EPA) review the reports and records of compliance to assess dental facilities' compliance with the pretreatment standards. These reports and records also allow Control Authorities to assess how many dentist offices within their jurisdiction discharge amalgam, what BMPs are used, when inspections occur as well as what operation and maintenance activities are conducted.

- 3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.**

The collection of information does not specify the use of automated, electronic, mechanical, or other technological collection techniques nor does it prevent the use of such techniques. EPA did not to specify electronic reporting in the regulation as it only requires a One-Time Compliance Report from each affected dental discharger.

- 4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose(s) described in item 2 above.**

This collection does not duplicate other information requests. Dental dischargers to POTWs have not previously been subject to reporting requirements for categorical dischargers, and therefore they were not required to submit the reports/certifications. There are no public sources available from which a Control Authority would be able to obtain this information.

5. If the collection of information impacts small businesses or other small entities, describe the methods used to minimize burden.

The regulation significantly reduces and streamlines the reporting requirements in EPA's General Pretreatment Regulations that would otherwise apply. Most significantly, it requires dental dischargers to submit a One-Time Compliance Report as described in Section A.1 rather than biannual reporting and wastewater sampling required of Categorical Industrial Users

6. Describe the consequence to federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The dental category regulation exempts dental offices from the General Pretreatment Regulations oversight and reporting requirements. Rather than requiring periodic compliance reporting, the regulation require a One-Time Compliance Report. Data submission less frequent than the One-Time Compliance Report could lower compliance rates and would prevent Control Authorities from knowing if dentists meet the requirements of the rule. This ICR presumes that all existing dental offices have submitted the One-Time Compliance Report. Therefore, only new dental offices which open during the ICR period and offices which transfer ownership during the ICR period will be submitting the One-Time Compliance Report.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than 3 years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The regulation requires that as long as the dental discharger is in operation (or until ownership is transferred) the discharger must maintain the One-Time Compliance Report. This may be for longer than three years. This allows dischargers to only complete the report one time, regardless of how long they are in business, rather than multiple times to keep retention times less than three years. Other than this requirement, the rule does not involve any of the above described special circumstances.

8. If applicable, identify the date and page number of publication in the Federal Register of the Agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB.

Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden any special circumstances that would cause an information collection to be conducted in a manner:

- **describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.**
- **consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.**

EPA solicited comments on this information collection request through publication of a notice in the *Federal Register*, per 5 CFR 1320.8(d) requirements, on April

30, 2020 (“Effluent Limitation Guidelines Dental Category (Renewal)”, docket ID EPA–HQ–OW–2020–0193; FRL–10008–67–OW, pp. 23959–23960). No comments were received during the 60-day comment period.

EPA also initiated a consultation with stakeholders in the American Dental Association (ADA), representing a majority of respondents. The consultation consisted of requesting input on availability of data, frequency of collection, clarity of reporting and recordkeeping requirements, whether electronic reporting would be an additional burden, and whether the data elements to be recorded are reasonable for the One-Time Certification Report. EPA received no comments during the consultation period.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

The regulation does not involve any payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Reports submitted to the Control Authority may contain confidential business information. However, EPA does not consider the specific information being requested by the regulation 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.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

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

12. Provide estimates of the hour burden of the collection of information. The statement should:

Hour Burden for Dentists: EPA estimates an average over the three-year period of this ICR of 122,741 dental offices would be subject to this ICR.

For the purposes of providing estimates under this ICR, dental offices subject to this ICR were further classified in the following four groups:

- Existing dental offices which do not place or remove amalgam;
- Existing dental offices which place or remove amalgam;
- Existing dental offices where there has been a transfer of ownership – regardless of amalgam use;
- New dental offices which place or remove amalgam.

It is assumed that all existing dental offices which place or remove amalgam have submitted the required One-Time Compliance Report. However, in the event a new dental office opens or a regulated dental discharger transfers ownership, the new owner must submit a One-Time Compliance Report (estimated to take 76 minutes or 1.27 hours per dental office).

EPA estimated a one percent growth rate for new dental offices and expects that 10 percent of dental offices which place or remove amalgam would transfer ownership each year. EPA assumed that the 407 military clinics/offices and dental schools which place or remove amalgam would neither increase in number or transfer ownership. As explained previously, EPA notes a One-Time Compliance Report is a reduction in burden that dental offices would otherwise experience under the reporting requirements that would apply to industrial users subject to an industry category regulation in 40 CFR Part 403.

EPA estimated an average annual labor burden of 1,565 hours per year (based on a three-year average) for One-Time Compliance Reporting at 1,235 newly opened dental offices. EPA estimated an average labor burden of 13,946 hours per year (based on a three-year average) for 11,010 dental offices transferring ownership. See Table 1.

EPA estimates that 110,496 dental offices that place or remove amalgam (based on a three-year average) would have recordkeeping costs. Dental offices that use or remove amalgam would need to keep on-site records of inspections, cleaning, maintenance, repair, and recycling. EPA estimates that one percent of dental offices will need a repair for their amalgam separator and will need to keep a record of it. EPA estimates that recordkeeping will require 200 minutes (or 3.34 hours) of burden per dental office, for an average annual labor burden of 368,874 hours per year (based on a three-year average). See Table 1.

The average annual labor for reporting and recordkeeping over a three-year period is 384,384 hours per year (based on a three-year average). See Table 1.

Hour Burden for Control Authorities:

As described above, the entity serving the role as the Control Authority varies. For purposes of this burden estimate, EPA estimates 37 States and 1,600 POTWs may serve as Control Authorities for Dental Dischargers. EPA estimates that State

and POTWs serve as the Control Authority for 88.28% of dental offices. For purposes of this ICR renewal, EPA assumed no Control Authorities would elect to perform oversight not required as a result of this regulation.

EPA estimated a one-time burden of 45 minutes associated for Control Authorities to review and file each One-Time Compliance Report for ownership transfers and for newly opened dental offices. EPA estimated an average annual labor burden for State and POTW Control Authorities of 7,329 hours per year to review and file One-Time Compliance Reports initiated due to transfer in ownership. This estimate is based on multiplying the estimated burden to review and file (0.75 hours/report) times the average annual number of dental offices that transferred ownership (110,693 total dental offices x 10% that transfer ownership x 88.28% reporting to State and POTW Control Authorities = 9,772 offices/year). EPA estimated an average annual labor burden for State and POTW Control Authorities of 933 hours per year to review and file One-Time Compliance Reports initiated due to newly opened dental offices. This estimate is based on multiplying the estimated burden to review and file (0.75 hours/report) times the average annual number of newly opened dental offices (1,415 new dental offices x 88.28% reporting to State and POTW Control Authorities = 1,244 offices/year). See Table 2.

The average annual labor for State and POTW Control Authority oversight over a three-year period is 8,262 hours. See Table 2.

Costs to Dentists: EPA estimated reporting costs for the average 110,496 dental offices for the specific activities related to the reporting requirements of the regulation. EPA estimated the labor costs for the proposed reporting requirements on average wages as reported for dental assistants from the Bureau of Labor Statistics in May 2018 (\$19.12/hour), which was adjusted in this ICR to include total compensation per guidance from the Bureau of Labor Statistics (\$27.31/hour). EPA used the estimated hours required to respond to the requirements of the regulation and multiplied these costs by this labor rate. EPA estimates an average annual labor cost of \$42,736 per year for the One-Time Compliance Reporting initiated by the opening of new dental offices. For transfers of ownership, EPA estimates an average annual labor cost of \$380,912 per year. EPA estimates an average annual labor cost of \$10,075,517 for recordkeeping.

Costs to Control Authorities: EPA estimated Control Authority costs for the specific activities related to oversight requirements. EPA based the labor costs for Control Authorities on average total compensation as reported for Control Authorities in Effluent Limitation Guidelines and Standards for the Metal Products and Machinery Category because this rule reported collected information on labor rates from Control Authorities. These costs reflect 1999 dollars. EPA took the 1999 labor rate and used the Employment Cost Index for State and Local Government Public Administration

(<https://www.bls.gov/ncs/ect/escalator.htm>) and converted the labor rate to 2019 dollars (\$67.45/hour). EPA used the estimated hours associated with oversight of the regulation and multiplied these costs by the 2019 labor rate. Where POTWs and states are Control Authorities, EPA estimated the annual average recordkeeping costs associated with One-Time Compliance Reporting for newly opened dental offices and those initiated by transfers of ownership to be \$557,2515.

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in items 12 and 14).

The majority of the burden and cost calculations in this ICR are the result of labor costs only. The ICR does, however, account for O&M costs to dental offices for reporting postage (average annual cost of \$6,735) and to State and POTW Control Authorities for storage of files (average annual cost of \$2,754).

See Tables 1 and 2 for O&M and labor costs for dental offices and State and POTW Control Authorities, respectively.

14. Provide estimates of annualized cost to the federal government.

Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from items 12, 13, and 14 in a single table.

For states that do not have authorized pretreatment programs, EPA will incur costs and burdens described for Control Authorities above. In a similar manner, EPA estimated that it would incur annual average labor burden costs associated with reviewing One-Time Compliance Reporting for newly opened dental offices and those initiated by transfer of ownership of \$73,708. EPA estimated that it would incur annual average file storage costs of \$362.

Table 1. Estimated Dental Office O&M Burden Hours and Labor Costs for New Dental Offices, Transfer of Ownership, and Recordkeeping (Questions 12 and 13)

Year / Activity	Estimated Labor Burden per Office (Minutes) ^a	Estimated Labor Burden per Office (\$) ^b	Number of Dental Offices Conducting Activity	Total Estimated Labor Burden (Hours) ^c	Total Estimated Labor Burden (\$) ^d	Total Estimated Postage Costs (\$) ^e	Total Estimated Burden (\$) ^f
Year 1 - One-time Compliance Form/Certification Form (New Offices)	76	\$34.59	1,223 ^g	1,549	\$42,312	\$673	\$42,984
Year 1 - Recordkeeping (Annual Cost)	200	\$91.18	109,403 ^h	365,223	\$9,975,792		\$9,975,792
Year 1 - Transfer of Ownership (Annual Cost)	76	\$34.59	10,900 ⁱ	13,807	\$377,128	\$5,995	\$383,123
Year 1 - Total Annual ^j			121,526	380,579	\$10,395,232	\$6,668	\$10,401,900
Year 2 - One-time Compliance Form/Certification Form (New Offices)	76	\$34.59	1,235 ^g	1,565	\$42,735	\$679	\$43,414
Year 2 - Recordkeeping (Annual Cost)	200	\$91.18	110,493 ^h	368,861	\$10,075,185		\$10,075,185
Year 2 - Transfer of Ownership (Annual Cost)	76	\$34.59	11,009 ⁱ	13,945	\$380,899	\$6,055	\$386,955
Year 2 - Total Annual ^j			122,737	384,371	\$10,498,819	\$6,734	\$10,505,554
Year 3 - One-time Compliance Form/Certification Form (New Offices)	76	\$34.59	1,248 ^g	1,580	\$43,162	\$686	\$43,848
Year 3 - Recordkeeping (Annual Cost)	200	\$91.18	111,594 ^h	372,537	\$10,175,572		\$10,175,572
Year 3 - Transfer of Ownership (Annual Cost)	76	\$34.59	11,119 ⁱ	14,085	\$384,708	\$6,116	\$390,824
Year 3 - Total Annual ^j			123,960	388,201	\$10,603,442	\$6,802	\$10,610,245
3-Year Average: One-time Compliance Form/Certification Form (New Offices)			1,235	1,565	\$42,736	\$679	\$43,416
3-Year Average: Recordkeeping (Annual Cost)			110,496	368,874	\$10,075,517		\$10,075,517

Table 1. Estimated Dental Office O&M Burden Hours and Labor Costs for New Dental Offices, Transfer of Ownership, and Recordkeeping (Questions 12 and 13)

Year / Activity	Estimated Labor Burden per Office (Minutes) ^a	Estimated Labor Burden per Office (\$) ^b	Number of Dental Offices Conducting Activity	Total Estimated Labor Burden (Hours) ^c	Total Estimated Labor Burden (\$) ^d	Total Estimated Postage Costs (\$) ^e	Total Estimated Burden (\$) ^f
3-Year Average: Transfer of Ownership (Annual Cost)			11,010	13,946	\$380,912	\$6,055	\$386,967
3-Year Average: All Activities ^j			122,741	384,384	\$10,499,165	\$6,735	\$10,505,899

^a The Estimated Burden per Office (Minutes) is based on EPA estimates of: the time required to input the data for compliance reports (76 minutes) and the time required to input the data for recordkeeping (200.3 minutes). Values for time required to complete these tasks have been rounded to three significant figures.

^b The Estimated Cost Burden per Office (\$) is based on the Estimated Burden per Office (Minutes) multiplied by the labor rate of \$27.31 per hour for a dental assistant. The base wage rate for a dental assistant (\$19.12) is derived from Bureau of Labor Statistics (May 2018), and is adjusted to reflect the assumption that the base wage rate is 70% of full compensation.

^c The Total Estimated Labor Burden (Hours) is based on the Estimated Burden per Office (Minutes) x Number of Dental Offices Conducting the Activity x 1 hour/60 minutes.

^d The Total Estimated Labor Burden (\$) is based on the Total Estimated Labor Burden (Hours) x the labor rate (\$27.31).

^e The Total Estimated Postage Costs (\$) is based on the number of dental offices performing this activity x the postage cost (\$0.55). This estimate assumes that the total number of dental offices increases by 1 percent each year and that these new dental offices file the One-Time Certification form. This estimate also assumes that 10% of the dental offices that place or remove amalgam file transfer ownership each year and file the Transfer of Ownership form.

^f The Total Estimated Burden is the sum of the Total Estimated Labor Burden (\$) and the Total Estimated Postage Costs (\$). Values may not add up exactly due to rounding.

^g The One-time Compliance Form/Certification Form is filed by new dental offices. This estimate assumes the total number of dental offices increases by 1 percent each year.

^h The Recordkeeping requirement is completed by the dental offices, dental clinics, and dental schools that place or remove amalgam and have technology costs. This estimate assumes the total number of dental offices increases by 1 percent each year.

ⁱ The Transfer of Ownership cost is incurred by dental offices that transfer ownership each year. This estimate assumes that 10% of the dental offices that place or remove amalgam transfer ownership each year. This estimate also assumes the total number of dental offices increases by 1 percent each year.

^j Columns may not add and values may not average due to rounding.

Table 2: Estimated Control Authority (States and POTWs) Oversight O&M Burden and Labor Costs (Questions 12 and 13)				
Activity	Labor Burden for New Offices (Hours)	Labor Burden for Ownership Transfer (Hours)	Total Estimated Labor Burden (Hours)^a	Total Estimated Cost Burden^b (\$)
Total in Year 1	924	7,256	8,180	\$554,381
Total in Year 2	933	7,329	8,262	\$560,025
Total in Year 3	942	7,402	8,344	\$565,609
Total Average Annual over Three-year period ^c	933	7,329	8,262	\$560,005

^a The Total Estimated Burden Hours is the sum of hours the Control Authority expends for reviewing the One-Time Recordkeeping and the Transfer of Ownership forms submitted by dental offices. The increase in Total Estimated Burden Hours assumes that the number of dental offices increase by one percent each year.

^b Total Estimated Cost Burden includes both labor costs and O&M (file storage) costs.

^c Values may not average exactly due to rounding.

Table 3. Summary of Total Burden and Costs for Respondents (Dentists) and Control Authorities (States and POTWs) Annually Over Three Years			
	Respondents	Annual Average Burden (Hours)	Annual Average Costs (\$)
Dental Offices	122,741	384,384	\$10,505,899
Control Authority (POTWs and States)	1,637	8,262	\$560,005
TOTAL Average Annual Over Three Years^a		392,646	\$11,065,904

^a Columns may not add due to rounding

15. Explain the reason for any program changes or adjustments in burden estimates from the previous approved ICR.

Because it is assumed that all existing dental offices which place or remove amalgam submitted the required One-Time Compliance Report during the prior ICR, the labor hours have decreased in this proposed ICR. However, the number of respondents and the labor rates increased. EPA is assuming a one percent growth rate in dental offices and that only new dental offices and dental offices transferring ownership will be doing the One-Time Compliance Reporting. EPA revised labor rates to 2018 dollars and included total compensation.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

The data will be used by Control Authorities for compliance and enforcement purposes. There are no plans for publication of the data.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

EPA is not seeking a waiver of the display requirements for the expiration date.

18. Explain each exception to the certification statement identified in item 19, "Certification for Paperwork Reduction Act Submissions," in ROCIS.

There are no exceptions to the certification statements.