

**INFORMATION COLLECTION REQUEST  
SUPPORTING STATEMENT**

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

**EPA ICR NUMBER 2514.02**

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

**November 11, 2017**

**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.**

EPA is promulgating standards 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 rule requires 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 amalgam separators and the use of two 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 place amalgam; or 2) that they are complying with the standards specified in the rule. They also must maintain on-site all records of compliance, as described in the regulation, and to make them available for inspection, upon request.

This ICR is seeking approval 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 collection of the information required in the regulation. Control Authorities may use their own form provided it meets the requirements of the regulation. To summarize the information requested in the sample one-time compliance form, the following section headers in the sample form 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)

This final rule includes a provision to significantly reduce and streamline the oversight and requirements that would otherwise apply as a result of this rulemaking. Control Authorities (which may be POTWs, states or the EPA) are responsible for oversight of the pretreatment standards. Oversight will be accomplished largely through the review of reports submitted by the dental offices.

EPA is promulgating 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.

- 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 new collection.

Control Authorities review the reports and records of compliance to assess dental facilities' compliance with the pretreatment standards.

- 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 received several comments requesting that EPA develop an electronic compliance reporting system as a part of this final rule. These commenters generally advocated for electronic reporting due to the size of the industry and the proposed annual reporting requirement. During development of the final rule, EPA considered several variations of requirements for dental dischargers to report electronically (which would have necessitated an electronic system). Most commonly, electronic systems are preferable when reports must be submitted on a periodic basis. EPA ultimately decided not to specify electronic reporting in the final rule after it determined the final rule would only require 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.**

The rule does not duplicate other information requirements. 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.**

This final rule includes a provision to significantly reduce and streamline the reporting requirements in EPA's General Pretreatment Regulations that would otherwise apply as a result of this rulemaking. Most significantly, it eliminates biannual reporting and wastewater sampling. Instead, it requires dental dischargers to submit a One-Time Compliance Report as described in Section A.1.

**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.**

Dental offices are not currently required to report the characteristics of their discharges to Control Authorities. As this rule requires a One-Time Compliance Report only, data submission less frequent than the One-Time Compliance Report would prevent Control Authorities from knowing if dentists meet the requirements of the rule.

**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 final rule contains a provision that may require a dental discharger to maintain the One-Time Compliance Report for longer than three years. The rule requires that as long as the dental discharger is in operation or ownership is transferred, the discharger must maintain the One-Time Compliance Report. 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.**

A summary of the ICR and request for public comment was included in the Federal Register notice for the proposed rule. (79 FR 63282, October 22, 2014).

EPA received numerous comments related to burden in the proposed rule (79 FR 63282, October 22, 2014), particularly from POTWs (many of which are Control Authorities). These commenters largely supported the reduced oversight requirements in the proposal, but encouraged EPA to reduce them further so that dental offices would never be SIUs, primarily due to concerns over the associated burden given the large number of dental offices potentially subject to the rule. In

addition, they raised concerns that they would have to update state and local laws to take advantage of the proposed changes to part 403 that would reduce the oversight requirements. They also raised concerns about additional reporting requirements for the Control Authorities typically associated with CIUs, such as identifying CIUs in their annual pretreatment report to the Approval Authority.

In response, EPA did not revise the General Pretreatment Standards to create the proposed DIU category and associated requirements. Rather, the final dental rule establishes for the purposes of Part 441, that dental dischargers are not SIUs or CIUs as defined in 40 CFR 403 unless designated as such by the Control Authority. This regulatory structure achieves the same goal as the proposed revisions to the General Pretreatment Standards without creating a need for updates to state and local laws. By establishing that dental dischargers are not SIUs or CIUs in the final rule, EPA eliminates the application of specific oversight and reporting requirements in 40 CFR Part 403 such as permitting and annual inspections of dental dischargers for SIUs and CIUs unless the Control Authority chooses to apply these requirements to dental offices. This means that Control Authorities have discretion under the final rule to determine the appropriate manner of oversight, compliance assistance, and enforcement. Further, the final rule reduced reporting for dental offices (and associated oversight requirements by Control Authorities) in comparison to reporting requirements for other industries subject to categorical pretreatment standards, as it requires only a One-Time Compliance Report be submitted to the Control Authority. The One-Time Compliance Report requirements specific to dental dischargers are included in this rule rather than in the General Pretreatment regulations so that they may be implemented directly.

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

The rule 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 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.

**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 rule 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:**

Dentists: EPA estimates 116,719 dental offices would be subject to today's final rule. Dental offices would complete a One-Time Compliance Report. EPA estimates that the completion of this report would take 76 minutes per dental office. Therefore, dental offices would require approximately 1 hour of labor associated with a One-Time Compliance Report. In the event a dental discharger transfers ownership of the facility, the new owner must submit a One-Time Compliance Report (also estimated to take 76 minutes per dental office). EPA estimated 10% of dental offices may transfer ownership form each subsequent year. As explained previously, EPA notes a One-Time Compliance Report 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 116,719 dental offices, EPA estimated a total one-time labor of 148,000 hours for the One-Time Compliance Report. For One-Time Compliance Reports required as a result of transfer of ownership, EPA estimated a total labor of 13,100 hours per year. See Table 1. Also see DCN DA00456.

For recordkeeping, EPA estimates that 103,034 offices, a subset of the dental offices those that place or remove amalgam, would have recordkeeping costs. Offices that place or remove amalgam, would need to keep on-site records of maintenance-related recordkeeping, recycling-related recordkeeping, and inspection-related recordkeeping. As well, EPA estimates that 1% of dental offices will need a repair for their amalgam separator and will need to keep a record of it. For recordkeeping, EPA estimates 200 minutes of burden per dental office, for a total labor of 344,000 hours per year. See DCN DA00456.

The total annual average labor hours over a three year period are 402,160 hours. See Table 3.

Control Authorities: The costs to Control Authorities for review of the reports required by the final rule are significantly reduced from the existing regulatory scheme. As explained above, because the final dental rule establishes that dental dischargers are not SIUs or CIUs, the required incremental oversight includes receipt of reports and other transfer of ownership notices submitted by dischargers.

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 no Control Authorities would elect to perform oversight not required as a result of this final rule.

EPA estimated one-time burden of 45 minutes associated for Control Authorities to review and file each One-Time Compliance Report (including the One-Time Compliance Report if ownership transfers). For States and POTWs that are Control Authorities, EPA estimates total one-time total labor of 76,900 hours. For One-Time Compliance Reports initiated due to transfer in ownership, EPA estimated total annual labor of 6,790 hours per year. For details on how EPA estimated each of the components, see DCN DA00457. Also see Table 2. The total annual average labor hours over a three year period are 30,200 hours. See Table 3.

**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).**

Dentists: EPA estimated reporting costs for the 116,719 dental offices for the specific activities related to the reporting requirements of the final 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, 2015 (\$17.75/hour). EPA used the estimated hours required to respond to the requirements of the final rule and multiplied these costs by this labor rate. EPA estimated a one-time cost of \$2,680,000 for reporting; as well, annual costs associated with One-Time Compliance Reporting initiated by transfer of ownership of \$237,000 starting in year 2.

For recordkeeping, 103,034 dental offices that place or remove amalgam would have recordkeeping costs. EPA used the same labor costs from BLS to estimate an annual cost of \$6,110,000 for the recordkeeping. See Table 1. Also, see DCN DA00456.

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 labor costs 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. EPA took the 1999 labor rate and using the Employment Cost Index for State and Local Government Public Administration converted to 2016 dollars (\$58.56/hour). EPA used the estimated hours associated with oversight of the final rule and multiplied these costs by this labor rate. Where POTWs and states are Control authorities, EPA estimated they will incur total one-time recordkeeping costs of \$4,530,000 and annual



recordkeeping costs associated with One-Time Compliance Reporting initiated by transfer of ownership of \$400,000. See Table 2. Also, see DCN DA00457.

- 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.**

Where EPA is the Control Authority, EPA will incur costs and burdens described for Control Authorities above. Where EPA is the Control Authority, EPA estimates total one-time total labor of 10,600 hours and recurring total annual labor of 937 hours. The total annual average labor hours are 4,160 hours. In a similar manner, EPA estimated that it would incur total one-time recordkeeping costs of \$625,000 and annual recordkeeping costs associated with One-Time Compliance Reporting initiated by transfer of ownership of \$55,200. The total annual average is \$245,000. See Table 4. For details on how EPA estimated Agency burden and costs, see DCN DA00457.

<b>Table 1. Estimated Dental Office Burden and Labor Costs for One-Time Compliance Reports (Including Transfer of Ownership) and Recordkeeping (Question 12 and 13)</b>					
<b>Activity</b>	<b>Estimated Burden Hours Per Office</b>	<b>Estimated Cost Burden Per Office<sup>a</sup></b>	<b>Number of Dental Offices Conducting Activity</b>	<b>Total Hours</b>	<b>Total Cost</b>
<b>Respondents (dental office)</b>					
Compliance Report	1.27	\$23	116,719	148,000	\$2,680,000
Recordkeeping Costs – Year 1	3.34	\$59	103,034	344,000	\$6,110,000
<b>Total Costs in Year 1</b>				<b>492,000</b>	<b>\$8,790,000</b>
Recordkeeping and Transfer of Ownership (One-Time Compliance Report) - Year 2	3.47	\$62	103,034	357,000	\$6,340,000
Recordkeeping and Transfer of Ownership (One-Time Compliance Report) Year 3	3.47	\$62	103,034	357,000	\$6,340,000
<b>Annual Average over Three Year Period</b>				<b>402,000</b>	<b>\$7,160,000</b>
a – Labor rate of \$17.75 per hour for a dental assistant based from Bureau of Labor Statistics (May, 2015). May not add due to rounding					

<b>Table 2: Estimated Control Authority (States and POTWs) Oversight Burden and Labor Costs (Question 12 and 13)</b>		
<b>Activity</b>	<b>Total Estimated Burden Hours</b>	<b>Total Estimated Cost Burden</b>
Total One-Time Burden for Control Authority	76,900	\$4,530,000
Total Costs in Year 1	76,900	\$4,530,000
Total Costs in Year 2	6,790	\$400,000
Total Costs in Year 3	6,790	\$400,000
Total Average Annual Cost over Three year period	<b>30,200</b>	<b>\$1,780,000</b>
May not add due to rounding		

**Table 3. Summary of Total Burden and Costs for Respondents (Dentists) and Control Authorities (States and POTWs) Annually Over Three Years**

	<b>Respondents</b>	<b>Total Annual Average Burden (Hours)</b>	<b>Total Annual Average Costs</b>
Dental Offices	116,719	402,000	\$7,160,000
Control Authority (POTWs and States)	1,636	30,200	\$1,780,000
<b>TOTAL Average Annual Over Three Years</b>		<b>432,000</b>	<b>\$8,930,000</b>
May not add due to rounding			

**Table 4. Summary of Total Burden and Costs for Agency (EPA) (Question 14) Annually Over Three Years**

	<b>Respondents</b>	<b>Total Annual Average Burden (Hours)</b>	<b>Total Annual Average Costs</b>
<b>EPA</b>	<b>9</b>	<b>4,160</b>	<b>\$245,000</b>
<b>TOTAL Average Annual Over Three Years</b>		<b>4,160</b>	<b>\$245,000</b>

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

This is a new collection.

- 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.