



# DENTAL AMALGAM RULE

## PRETREATMENT STANDARD AND PROGRAM IMPLEMENTATION

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RVIPA 35<sup>th</sup> Annual Pretreatment Workshop  
Wednesday, August 7, 2019

# DENTAL PRETREATMENT STANDARDS – 40 CFR PART 441

- Rule overview: **Effective July 14, 2017**
- Dental offices that place or remove amalgam must operate and maintain an **amalgam separator** (or equivalent device) and must not discharge scrap amalgam or use certain kinds of line cleaners
- One-time compliance report and recordkeeping requirements
- The rule is
  - self-implementing
  - minimizes the administrative burden to federal, state, and local regulatory authorities responsible for oversight of the new requirements



# WHAT IS AN AMALGAM SEPARATOR?

- It is a solids collector
  - Designed to capture solids so that they can be recycled and disposed of properly
  - Captures mercury by default, not by design
  - Commonly designed to capture ~99% of solids by weight not mercury
- EPA estimates that dental offices that do not currently have separators will incur an approximate average
  - annual cost of \$800 per office.
  - Unit price from ~\$400 to ~\$1000



# DENTAL PRETREATMENT STANDARDS – 40 CFR PART 441

- Existing source required compliance date:  
**October 12, 2020**
- New Sources required to comply as of effective date  
**July 14, 2017**



# DENTAL PRETREATMENT STANDARDS – 40 CFR PART 441

- The American Dental Association (ADA) is working with EPA to help publicize this rule and to help dentists understand any applicable requirements
- EPA developed 2 **FAQs** to help Dentists and Control Authorities
  - [Frequently Asked Questions for Control Authorities on the Dental Rule \(40 CFR Part 441\)](#)
  - [Frequently Asked Questions on the Dental Office Category Rule](#)

# APPLICABILITY

40 CFR 441.10

- The final rule applies to wastewater discharges to **POTWs** from offices where the practice of dentistry is performed, including
  - large institutions such as dental **schools** and **clinics**;
  - **permanent** or **temporary** offices,
  - **home** offices, and facilities; and
  - dental offices owned and operated by **federal, state, or local** governments including **military** bases.

# APPLICABILITY

40 CFR 441.10

## Rule does NOT apply to

- Dental dischargers that **exclusively** practice one or more of the following dental specialties:
  - Oral pathology
  - oral and maxillofacial radiology
  - oral and maxillofacial surgery
  - orthodontics
  - periodontics
  - prosthodontics

# APPLICABILITY

40 CFR 441.10

## **Rule does NOT apply to (continued)**

- Mobile units
- Dental dischargers that do not discharge any amalgam process wastewater to a POTW including those that discharge to a septic system
- Dentists that transfer waste to a Centralized Waste Treatment Facility

# APPLICABILITY

40 CFR 441.10

## Exemptions from certain requirements:

- Dentists otherwise subject to the rule are exempt from all except reporting requirements if they:
  1. Do **NOT** place or remove amalgam except in limited **emergency, unplanned, unanticipated** circumstances  
AND
  2. Complete one-time compliance report to certify as such

# AMALGAM SEPARATOR DEVICE REQUIREMENTS

- Rule requires one or more 2008 ISO 11143 compliant amalgam separators (or an equivalent device)
  - EPA does not expect dentists to demonstrate a separator is compliant but rather that manufacturers will obtain the required demonstration and make that information available
- Rule allows dentists that had installed and were using an amalgam separator prior to June 14, 2017 to continue to use it until **June 14, 2027** if it is functioning properly and does not need to be replaced; this is referred to as a “grandfathering” provision
  - Dentists should follow manufacturer’s instructions to determine if a separator needs to be replaced
- Rule does not require that separators be replaced every 10 years. Ten years only applies to the grandfathering provision

# AMALGAM SEPARATOR OPERATION AND MAINTENANCE REQUIREMENTS

- Apply to new and grandfathered separators and include:
  - inspection in accordance with the manufacturer's operating manual to ensure proper operation and maintenance of the separator(s) and to confirm that all amalgam process wastewater is flowing through the amalgam retaining portion of the amalgam separator(s)
  - repair or replacement of the separator as needed; if not functioning properly, must be repaired or replaced within **10 business days** after the malfunction is discovered
  - replacement of the amalgam retaining unit in accordance with the manufacturer's operating manual or when the amalgam retaining unit has reached the maximum level, whichever comes first
- Rule does not specify training or certification requirements for those that inspect or maintain the separator

# AMALGAM SEPARATOR

## OPERATION AND MAINTENANCE REQUIREMENTS (CONTINUED)

- Collected solids must be handled in accordance with federal (RCRA), state and local requirements
- Some amalgam separator vendors (in addition to providing the needed equipment) or service providers offer service contracts to maintain the system
  - These vendors also typically provide waste management services for the collected solids
  - EPA encourages but does not require dental offices to consider such services, as they may aid in compliance with the rule

# RECORDKEEPING REQUIREMENTS

- Rule requires dental offices to document certain operation and maintenance requirements and maintain all records of compliance, as described in the regulation, and to make them available for inspection
  - The dental office, or an agent or representative of the dental office, must maintain these records and make available for inspection in either physical or electronic form, for a minimum of **three years**
- As long as a dental office is in operation, or until ownership is transferred, the dentist or an agent or representative of the dentist must maintain the one-time compliance report and make it available for inspection in either physical or electronic form
- The dental office, or an agent or representative of the dental office, should also maintain either a physical or electronic copy of the manufacturer's operating manual for the current device

# BEST MANAGEMENT PRACTICES

- The final rule requires that dental offices must not discharge waste amalgam (e.g., dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices)
- The final rule requires that dental offices must not clean dental unit water lines, chair-side traps, and vacuum lines that discharge amalgam process wastewater with **oxidizing or acidic cleaners**
  - In the regulation, the clause that follows (“including but not limited to...”) is not an exhaustive list of oxidizing or acidic cleaners or qualities that make a cleaner oxidizing or acidic. For example, a cleaner that is oxidizing would be prohibited even if its pH is between 6 and 8

# ONE-TIME COMPLIANCE REPORT

- Report to include: Facility name, physical address, mailing address, contact information, name of the operator(s) and owner(s); and a certification statement that the design and operation of the separator meets the requirements in 441.40 or 441.50 and that the facility is employing the BMP's specified
- EPA's dental rule website includes a sample one-time compliance report that contains the minimum information dental facilities must submit in a one-time compliance report as required by the 40 CFR part 441 ("Dental Amalgam Rule").
- Control Authorities are not required to use this sample report
- This report is in lieu of the otherwise applicable reporting requirements in 40 CFR part 403 (e.g., baseline monitoring report)

## Effluent Guidelines

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# Dental Effluent Guidelines

EPA has promulgated pretreatment standards to



## Reporting Requirements

Existing and new sources must submit a one-time compliance report to their pretreatment **Control Authority**. See the Federal Register notice for details.

## Who is my Control Authority?

Your Control Authority is either a local wastewater utility, a state environmental agency, or a U.S. EPA regional office.

## Dental offices in Alabama, Connecticut, Mississippi, Nebraska or Vermont

Your Control Authority is your **state agency**.

- [State Agency Contacts](#)

## Dental offices in all other states

Contact your EPA regional office, your local wastewater utility, or your state agency Pretreatment Coordinator to find out who your Control Authority is.

- [Pretreatment Program Contacts](#)

## Sample Compliance Report

This compliance report is an example. Your Control Authority may have a different form. Contact your Control Authority to determine which form to use. This sample form has not been approved by Office of Management and Budget under the Paperwork Reduction Act, and is subject to change.

- [Sample Dental Office Compliance Report \(DOCX\)](#) (4 pp, 40 K, September 2017) FREE VIEWERS 19

Go to  
[www.epa.gov/eg/dental-effluent-guidelines](https://www.epa.gov/eg/dental-effluent-guidelines)

Scroll down to “Reporting Requirements”

See Control Authority information and Sample Compliance Report

# CONTROL AUTHORITY OVERSIGHT/REPORTING

- Rule specifies that dental dischargers are not significant industrial users (SIUs) or categorical industrial users (CIUs) as defined in 40 CFR 403 unless designated as such by the Control Authority
- By establishing that dental dischargers are not SIUs or CIUs in the final rule, EPA eliminated the application of specific oversight and reporting requirements in 40 CFR 403 such as permitting and annual inspections of dental dischargers unless the Control Authority chooses to apply these requirements to dental offices
  - This means that Control Authorities have discretion under the final rule to determine the appropriate manner of oversight, compliance assistance, and enforcement (including tracking compliance with the rule's requirements)
  - It also eliminates additional reporting requirements for the Control Authorities typically associated with CIUs, such as identification of CIUs in their annual pretreatment reports
- **In summary, the only incremental change for Control Authorities is that they must receive the One-Time Compliance Reports from dental dischargers and retain that notification according to the standard records retention protocol contained in 403.12(o)**

# CONTROL AUTHORITY OVERSIGHT (CONTINUED)

- The rule recognizes the Control Authority's discretionary authority to treat a dental discharger as an SIU and/or CIU if, in the Control Authority's judgement, it is necessary
- The rule does not change existing federal Control Authority oversight requirements for industrial users
  - As the General Pretreatment Requirements specify an industrial user (IU) to be a nondomestic source of indirect discharge into a POTW, this rule does not change the "IU" status of a dental discharger
  - This rule does not alter enforcement plans for IUs
- This rule does not force POTWs without pretreatment programs to develop pretreatment programs
- The rule is self-implementing and it is the dentist's responsibility to know and comply with the rule

# QUESTIONS?

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