

Guide for the Implementation of Pretreatment Standards & Best Management Practices (BMPs) for Dental Dischargers

Brought to you by the Department for Regulatory Affairs, Environmental Compliance, Health and Occupational Safety of the Puerto Rico Aqueducts and Sewer Authority (PRASA).

Purpose

Dental practitioners offer among their services restoring teeth that have cavities by using dental amalgam. The Environmental Protection Agency (EPA) describes dental amalgam as a silver-colored material used as a tooth filling in the practice of dentistry, which is made of two nearly equal parts of liquid mercury and a powder containing silver, tin copper, zinc, and/or other metal. Furthermore, it is considered a safe and effective treatment for tooth decay by the U.S. Food and Drug Administration (FDA). However, the improper disposal of dental amalgam can have direct or indirect detrimental effects on human health and the environment. While the FDA is responsible for ensuring the safety and effectiveness of dental amalgam as well as proper product labelling for dentists, it is the responsibility of other regulatory agencies, including EPA and local agencies such as PRASA, to ensure that the disposal of any residual dental amalgam waste is not released into the environment. Dental offices are the largest source of mercury at Publicly Owned Treatment Works (POTW), and it is therefore important to ensure that any dental user which may discharge dental amalgam into the sewer system of PRASA is in compliance with any and all regulatory pretreatment standards. As part of PRASA's mission to return clean water to the environment, the Pretreatment Program developed this guide to assist users that qualify as Dental Dischargers to comply with any applicable federal pretreatment standards.

Objectives

- Protect human health, the environment and the sanitary infrastructure of PRASA's POTW.
- Ensure compliance with local and federal regulations.
- Provide information regarding the pretreatment standards established in 40 CFR § 441 applicable to Dental Dischargers.
- Provide applicable Dental Dischargers the rules, regulatory requirements, and deadlines they need to comply with, including:
 - installation, operation and management of proper equipment,
 - implementation of best management practices,
 - submitting the appropriate records,
 - and implementing proper recordkeeping practices.

Applicability & Local Requirements

The Rules and Regulations for the Supply of Water and Sewer Service (the Ordinance) of PRASA establish requirements applicable to all dischargers of waste to the treatment works of PRASA. In accordance with Section 2.04(B) of the Ordinance, *no user shall discharge, or cause to be discharged* any pollutant or wastewater which passes through or interferes with the operation or performance of a treatment works, and all new discharges shall be in compliance with the general discharge prohibitions prior to commencing discharge. Furthermore, on June 14th, 2017, EPA established Pretreatment Guidelines and Standards for the Dental Category (40 CFR § 441) that became effective on July 14th, 2017. In order to be in compliance with both local and federal standards, all applicable Dental Dischargers must:

- I. Achieve removal of dental amalgam solids from all amalgam process wastewater by one of the methods established in § 441.30(a) and meet the standards set forth in § 441.30 for existing sources and § 441.40 for new sources.
- II. Implement the two (2) Best Management Practices (BMPs) listed in § 441.30(b).
- III. Submit a **One-Time Compliance Report**, maintain a record of the report and make it available for inspection in accordance with § 441.50(a)(1) and (5).
- IV. Make available for inspection in either physical or electronic form for a minimum of three (3) years all the necessary documentation listed in § 441.50(b).

In accordance with § 441.10, all Dental Dischargers are subject to the pretreatment standards set forth in § 441.30 or 441.40, as applicable. However, the standards do not apply to the following:

- 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
- Wastewater discharges from a mobile unit operated by a dental discharger.
- Dental Dischargers that do not discharge any amalgam process wastewater to a POTW, such as Dental Dischargers that collect all dental amalgam process wastewater for transfer to a **Centralized Waste Treatment facility** defined as - *Any facility that treats (for disposal, recycling or recovery of material) any hazardous or non-hazardous industrial wastes, hazardous or non-hazardous industrial wastewater, and/or used material received from off-site. "CWT facility" includes both a facility that treats waste received*

exclusively from off-site and a facility that treats wastes generated on-site as well as waste received from off-site. For example, an organic chemical manufacturing plant may, in certain circumstances, be a CWT facility if it treats industrial wastes received from offsite as well as industrial waste generated at the organic chemical manufacturing plant. CWT facilities may also include re-refiners and may be owned by the federal government. [40 CFR § 437.2 (c)]

- Furthermore, Dental Dischargers that do not place dental amalgam, and do not remove amalgam except in limited emergency or unplanned, unanticipated circumstances are required to certify such to PRASA in a **One-Time Compliance Report** and maintain the One-Time Compliance Report as specified in § 441.50(a)(1), (3)(i) and (5), and are exempt from any further requirements of § 441.

I. Pretreatment Standards [40 CFR § 441.30(a)]

The following pretreatment standards apply to new and existing sources of dental discharges subject to 40 CFR § 441. Existing sources of dental discharges must achieve the pretreatment standards by no later than **July 14, 2020**. In accordance with § 441.40, *as of July 14, 2017*, any new source of Dental Discharges must comply with the pretreatment standards.

All Dental Dischargers must achieve the removal of dental amalgam solids from all amalgam process wastewater by installing, operating and maintaining either of the following types of equipment (refer to Appendix A for further specifications):

1. One or more **Amalgam Separator(s)** in accordance with §441.30(a)(1).
2. One or more **Amalgam Removal Device(s)** in accordance with §441.30(a)(2).

As a “grandfathering” clause, a Dental Discharger subject to the Rule that operates an amalgam separator that was installed at a dental facility prior to June 14, 2017, satisfies the requirements of paragraphs (a)(1)(i) and (ii) of § 441.30 until the existing separator is replaced as described in paragraph (a)(1)(v) of § 441.30 or until **June 14, 2027**, whichever is sooner.

II. Best Management Practices [40 CFR § 441.30(b)]

Existing sources of dental discharges subject to 40 CFR § 441 must implement the following BMPs by no later than **July 14, 2020**, and new sources must implement the BMPs as of **July 14, 2017**.

All Dental Dischargers must implement the following two (2) BMPs and certify that they will continue to do so, in accordance with §441.50(a)(3)(ii)(E):

1. **Waste amalgam** including, but not limited to, dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices, **must not be discharged to a POTW.**
2. **Dental unit water lines**, chair-side traps, and vacuum lines that discharge amalgam process wastewater to a POTW **must not be cleaned with oxidizing or acidic cleaners**, including but not limited to bleach, chlorine, iodine and peroxide that have a pH lower than 6 or greater than 8.

III. Reporting Requirements: *One-Time Compliance Report* [40 CFR § 441.50(a)]

In accordance with §441.50(a)(1), a dental discharger subject to the regulation must submit a **One-Time Compliance Report** to PRASA that complies, as applicable, with the following:

DEADLINES	
EXISTING SOURCES	NEW SOURCES
Must be submitted to PRASA no later than August 14, 2020 or 90 days after a transfer of ownership. PRASA must submit to EPA no later than October 12, 2020.	Must be submitted to PRASA no later than 90 days following the introduction of wastewater into a POTW.

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<p>For Dental Dischargers subject to the standards in § 441 must include:</p> <ul style="list-style-type: none"> • Facility name • Physical address • Mailing address • Contact information • Name of the Operator(s) and owner(s) • A description of the operations at the dental facility including: <ul style="list-style-type: none"> ○ Total number of chairs ○ Total number of chairs at which dental amalgam may be present in the resulting wastewater. ○ Description of any existing amalgam separator(s) or equivalent device(s) currently operated including, at a minimum, the make, model, and year of installation. • Certification that the amalgam separator(s) or equivalent device is designed and will be operated and maintained to meet the requirements specified in §441.30 or §441.40. • Certification that the dental discharger is implementing BMPs specified in §441.30(b) or §441.40 and will continue to do so. • The name of the third-party service provider that maintains the amalgam separator(s) or equivalent device(s) operated at the dental facility, if applicable. Otherwise, a brief description of the practices employed by the facility to ensure proper operation and maintenance in accordance with §441.30 or §441.40.

For Dental Dischargers **subject to the standards in § 441 that do not place or remove dental amalgam and do not remove amalgam except in limited emergency or unplanned, unanticipated circumstances**, the One-Time Compliance Report must include:

- Facility Name
- Physical Address
- Mailing Address
- Contact Information
- Name of the Operator(s) and owner(s)
- Certification statement that the dental discharger does not place dental amalgam and does not remove amalgam except in limited circumstances.

NOTIFICATION TRANSFER OF OWNERSHIP

If a dental discharger transfers ownership of the facility, the new owner must submit a new One-Time Compliance Report to the Control Authority no later than 90 days after the transfer.

SIGNATURE AND CERTIFICATION

The One-Time Compliance Report must be signed and certified by a responsible corporate officer, a general partner or proprietor if the dental discharger is a partnership or sole proprietorship, or a duly authorized representative in accordance with the requirements of 40 CFR 403.12(l).

IV. Recordkeeping Requirements [40 CFR § 441.50(b)]

A dental discharger or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form the following records:

1. **One-Time Compliance Report** – As long as a Dental Discharger subject to §441 is in operation, or until ownership is transferred, the Dental Discharger or an agent or representative of the dental discharger must maintain the **One-Time Compliance Report** as required at **Section III** and make it available for inspection in either physical or electronic form, as required in §441.50(a)(5).

The remaining records must be maintained for a minimum of **three (3) years**:

2. **Inspection Records** – Documentation of the date, person(s) conducting the inspection, results of each inspection of the amalgam separator(s) or equivalent device(s), and a summary of follow-up actions, if needed.
3. **Container Records** – Documentation of the amalgam retaining container or equivalent container replacement (including date, as applicable).
4. **Dental Amalgam Disposition Records** – Documentation of all dates that collected dental amalgam is picked up or shipped for proper disposal in accordance with 40 CFR 261.5(g)(3), and the name of the permitted or licensed treatment, storage or disposal facility receiving the amalgam retaining containers.

5. **Repairs & Replacements Records** – Documentation of any repair or replacement of an amalgam separator or equivalent device, including the date, person(s) making the repair or replacement, and a description of the repair or replacement (including make and model).
6. **Manufacturer’s Manual** – Dischargers or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form the manufacturers operating manual for the current device.

References

- 40 CFR § 261.5 [Reserved]
- 40 CFR § 437.2(c) – *The Centralized Waste Treatment Point Source Category – General Definitions* – **Centralized Waste Treatment (CWT) facility** means any facility that treats (for disposal, recycling or recovery of material) any hazardous or non-hazardous industrial wastes, hazardous or non-hazardous industrial wastewater, and/or used material received from off-site. “CWT facility” includes both a facility that treats waste received exclusively from off-site and a facility that treats wastes generated on-site as well as waste received from off-site. For example, an organic chemical manufacturing plant may, in certain circumstances, be a CWT facility if it treats industrial wastes received from offsite as well as industrial waste generated at the organic chemical manufacturing plant. CWT facilities may also include re-refiners and may be owned by the federal government.
- 40 CFR § 441 – *Dental Office Point Source Category*.
- Rules and Regulations for the Supply of Water and Sewer Service (The Ordinance). Ordinance number 6685 of June 2003:
 - Rules and Regulations for the Supply of Water and Sewer Service (<https://bit.ly/38QQJU1>)

Appendix A

Code of Federal Regulations – Title 40: Protection of Environment – Chapter I: Environmental Protection Agency – Subchapter N: Effluent Guidelines and Standards – Part 441: Dental Office Point Source Category

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AUTHORITY: 33 U.S.C. 1251, 1311, 1314, 1316, 1317, 1318, 1342, and 1361. 42 U.S.C. 13101-13103.
SOURCE: 82 FR 27176, June 14, 2017, unless otherwise noted.

§441.10 Applicability.

(a) Except as provided in paragraphs (c), (d), and (e) of this section, this part applies to Dental Dischargers.

(b) Unless otherwise designated by the Control Authority, Dental Dischargers subject to this part are not Significant Industrial Users as defined in 40 CFR part 403, and are not “Categorical Industrial Users” or “industrial users subject to categorical pretreatment standards” as those terms and variations are used in 40 CFR part 403, as a result of applicability of this rule.

(c) This part 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, or prosthodontics.

(d) This part does not apply to wastewater discharges from a mobile unit operated by a dental discharger.

(e) This part does not apply to Dental Dischargers that do not discharge any amalgam process wastewater to a POTW, such as Dental Dischargers that collect all dental amalgam process wastewater for transfer to a Centralized Waste Treatment facility as defined in 40 CFR part 437.

(f) Dental Dischargers that do not place dental amalgam, and do not remove amalgam except in limited emergency or unplanned, unanticipated circumstances, and that certify such to the Control Authority as required in §441.50 are exempt from any further requirements of this part.

§441.20 General definitions.

For purposes of this part:

(a) *Amalgam process wastewater* means any wastewater generated and discharged by a dental discharger through the practice of dentistry that may contain dental amalgam.

(b) *Amalgam separator* means a collection device designed to capture and remove dental amalgam from the amalgam process wastewater of a dental facility.

(c) *Control Authority* is defined in 40 CFR 403.3(f).

(d) *Dental amalgam* means an alloy of elemental mercury and other metal(s) that is used in the practice of dentistry.

(e) *Dental Discharger* means a facility where the practice of dentistry is performed, including, but not limited to, institutions, permanent or temporary offices, clinics, home offices, and facilities owned and operated by Federal, state or local governments, that discharges wastewater to a publicly owned treatment works (POTW).

(f) *Duly Authorized Representative* is defined in 40 CFR 403.12(l)(3).

(g) *Existing Sources* means a dental discharger that is not a new source.

(h) *Mobile unit* means a specialized mobile self-contained van, trailer, or equipment used in providing dentistry services at multiple locations.

(i) *New Sources* means a dental discharger whose first discharge to a POTW occurs after July 14, 2017.

(j) *Publicly Owned Treatment Works* is defined in 40 CFR 403.3(q).

§441.30 Pretreatment standards for existing sources (PSES).

No later than July 14, 2020, any existing source subject to this part must achieve the following pretreatment standards:

(a) Removal of dental amalgam solids from all amalgam process wastewater by one of the following methods:

(1) Installation, operation, and maintenance of one or more amalgam separators that meet the following requirements:

(i) Compliant with either the American National Standards Institute (ANSI) American National Standard/American Dental Association (ADA) Specification 108 for Amalgam Separators (2009) with Technical Addendum (2011) or the International Organization for Standardization (ISO) 11143 Standard (2008) or subsequent versions so long as that version requires amalgam separators to achieve at least a 95% removal efficiency. Compliance must be assessed by an accredited testing laboratory under ANSI's accreditation program for product certification or a testing laboratory that is a signatory to the International Laboratory Accreditation Cooperation's Mutual Recognition Arrangement. The testing laboratory's scope of accreditation must include ANSI/ADA 108-2009 or ISO 11143.

(ii) The amalgam separator(s) must be sized to accommodate the maximum discharge rate of amalgam process wastewater.

(iii) A dental discharger subject to this part that operates an amalgam separator that was installed at a dental facility prior to June 14, 2017, satisfies the requirements of paragraphs (a)(1)(i) and (ii) of this section until the existing separator is replaced as described in paragraph (a)(1)(v) of this section or until June 14, 2027, whichever is sooner.

(iv) The amalgam separator(s) must be inspected 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).

(v) In the event that an amalgam separator is not functioning properly, the amalgam separator must be repaired consistent with manufacturer instructions or replaced with a unit that meets the requirements of paragraphs (a)(i) and (ii) of this section as soon as possible, but no later than 10 business days after the malfunction is discovered by the dental discharger, or an agent or representative of the dental discharger.

(vi) The amalgam retaining units must be replaced in accordance with the manufacturer's schedule as specified in the manufacturer's operating manual or when the amalgam retaining unit has reached the maximum level, as specified by the manufacturer in the operating manual, at which the amalgam separator can perform to the specified efficiency, whichever comes first.

(2) Installation, operation, and maintenance of one or more amalgam removal device(s) other than an amalgam separator. The amalgam removal device must meet the following requirements:

(i) Removal efficiency of at least 95 percent of the mass of solids from all amalgam process wastewater. The removal efficiency must be calculated in grams recorded to three decimal places, on a dry weight basis. The removal efficiency must be demonstrated at the maximum water flow rate through the device as established by the device manufacturer's instructions for use.

(ii) The removal efficiency must be determined using the average performance of three samples. The removal efficiency must be demonstrated using a test sample of dental amalgam that meets the following particle size distribution specifications: 60 percent by mass of particles that pass through a 3150 μm sieve but which do not pass through a 500 μm sieve, 10 percent by mass of particles that pass through a 500 μm sieve but which do not pass through a 100 μm sieve, and 30 percent by mass of particles that pass through a 100 μm sieve. Each of these three specified particle size distributions must contain a representative distribution of particle sizes.

(iii) The device(s) must be sized to accommodate the maximum discharge rate of amalgam process wastewater.

(iv) The device(s) must be accompanied by the manufacturer's manual providing instructions for use including the frequency for inspection and collecting container replacement such that the unit is replaced once it has reached the maximum filling level at which the device can perform to the specified efficiency.

(v) The device(s) must be inspected in accordance with the manufacturer's operation manual to ensure proper operation and maintenance, including confirmation that amalgam process wastewater is flowing through the amalgam separating portion of the device(s).

(vi) In the event that a device is not functioning properly, it must be repaired consistent with manufacturer instructions or replaced with a unit that meets the requirements of paragraphs (a)(2)(i) through (iii) of this section as soon as possible, but no later than 10 business days after the malfunction is discovered by the dental discharger, or an agent or representative of the dental discharger.

(vii) The amalgam retaining unit(s) of the device(s) must be replaced as specified in the manufacturer's operating manual, or when the collecting container has reached the maximum filling level, as specified by the manufacturer in the operating manual, at which the amalgam separator can perform to the specified efficiency, whichever comes first.

(viii) The demonstration of the device(s) under paragraphs (a)(2)(i) through (iii) of this section must be documented in the One-Time Compliance Report.

(b) Implementation of the following best management practices (BMPs):

(1) Waste amalgam including, but not limited to, dental amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices, must not be discharged to a POTW.

(2) Dental unit water lines, chair-side traps, and vacuum lines that discharge amalgam process wastewater to a POTW must not be cleaned with oxidizing or acidic cleaners, including but not limited to bleach, chlorine, iodine and peroxide that have a pH lower than 6 or greater than 8.

(c) All material is available for inspection at EPA's Water Docket, EPA West, 1301 Constitution Avenue NW., Room 3334, Washington, DC 20004, Telephone: 202-566-2426, and is available from the sources listed below.

(1) The following standards are available from the American Dental Association (ADA), 211 East Chicago Ave., Chicago IL 60611-2678, Telephone 312-440-2500, <http://www.ada.org>.

(i) ANSI/ADA Specification No. 108:2009, American National Standard/American Dental Association Specification No. 108 Amalgam Separators. February 2009.

(ii) ANSI/ADA Specification No. 108:2009 Addendum, American National Standard/American Dental Association Specification No. 108 Amalgam Separators, Addendum. November 2011.

(2) The following standards are available from the American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, Telephone 212-642-4900, <http://webstore.ansi.org>.

(i) International Standard ISO 11143:2008, Dentistry—Amalgam Separators. Second edition, July 1, 2008.

(ii) [Reserved]

[82 FR 27176, June 14, 2017; 82 FR 28777, June 26, 2017; 82 FR 30997, July 5, 2017]
§441.40 Pretreatment standards for new sources (PSNS).

As of July 14, 2017, any new source subject to this part must comply with the requirements of §441.30(a) and (b) and the reporting and recordkeeping requirements of §441.50.

§441.50 Reporting and recordkeeping requirements.

(a) Dental Dischargers subject to this part must comply with the following reporting requirements in lieu of the otherwise applicable requirements in 40 CFR 403.12(b), (d), (e), and (g).

(1) *One-Time Compliance Report deadlines.* For existing sources, a One-Time Compliance Report must be submitted to the Control Authority no later than October 12, 2020, or 90 days after a transfer of ownership. For new sources, a One-Time Compliance Report must be submitted to the Control Authority no later than 90 days following the introduction of wastewater into a POTW.

(2) *Signature and certification.* The One-Time Compliance Report must be signed and certified by a responsible corporate officer, a general partner or proprietor if the dental discharger is a partnership or sole proprietorship, or a duly authorized representative in accordance with the requirements of 40 CFR 403.12(l).

(3) *Contents.*

(i) The One-Time Compliance Report for Dental Dischargers subject to this part that do not place or remove dental amalgam as described at §441.10(f) must include the: facility name, physical address, mailing address, contact information, name of the

operator(s) and owner(s); and a certification statement that the dental discharger does not place dental amalgam and does not remove amalgam except in limited circumstances.

(ii) The One-Time Compliance Report for Dental Dischargers subject to the standards of this part must include:

(A) The facility name, physical address, mailing address, and contact information.

(B) Name(s) of the operator(s) and owner(s).

(C) A description of the operation at the dental facility including: The total number of chairs, the total number of chairs at which dental amalgam may be present in the resulting wastewater, and a description of any existing amalgam separator(s) or equivalent device(s) currently operated to include, at a minimum, the make, model, year of installation.

(D) Certification that the amalgam separator(s) or equivalent device is designed and will be operated and maintained to meet the requirements specified in §441.30 or §441.40.

(E) Certification that the dental discharger is implementing BMPs specified in §441.30(b) or §441.40(b) and will continue to do so.

(F) The name of the third-party service provider that maintains the amalgam separator(s) or equivalent device(s) operated at the dental office, if applicable. Otherwise, a brief description of the practices employed by the facility to ensure proper operation and maintenance in accordance with §441.30 or §441.40.

(4) *Transfer of ownership notification.* If a dental discharger transfers ownership of the facility, the new owner must submit a new One-Time Compliance Report to the Control Authority no later than 90 days after the transfer.

(5) *Retention period.* As long as a Dental Discharger subject to this part is in operation, or until ownership is transferred, the Dental Discharger or an agent or representative of the dental discharger must maintain the One-Time Compliance Report required at paragraph (a) of this section and make it available for inspection in either physical or electronic form.

(b) Dental Dischargers or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form, for a minimum of three years:

(1) Documentation of the date, person(s) conducting the inspection, and results of each inspection of the amalgam separator(s) or equivalent device(s), and a summary of follow-up actions, if needed.

(2) Documentation of amalgam retaining container or equivalent container replacement (including the date, as applicable).

(3) Documentation of all dates that collected dental amalgam is picked up or shipped for proper disposal in accordance with 40 CFR 261.5(g)(3), and the name of the permitted or licensed treatment, storage or disposal facility receiving the amalgam retaining containers.

(4) Documentation of any repair or replacement of an amalgam separator or equivalent device, including the date, person(s) making the repair or replacement, and a description of the repair or replacement (including make and model).

(5) Dischargers or an agent or representative of the dental discharger must maintain and make available for inspection in either physical or electronic form the manufacturers operating manual for the current device.