



Dental Discharger's One-Time Compliance Report

GENERAL INFORMATION

Name of Dental Facility					
Physical Address of Dental Facility					
(Street Address must include Building and/or Suite ID)					
City:		State:		Zip:	
Mailing Address					
City:		State:		Zip:	
Name of Facility Contact			Title		
Phone:		Email:			
Name of Owner/Operator(s)					

Dental Business Ownership Type:	<input type="checkbox"/> Sole Proprietorship	<input type="checkbox"/> Partnership	<input type="checkbox"/> Corporation
	<input type="checkbox"/> Governmental Agency	<input type="checkbox"/> Other Institutional Organization	
Starting Date of Dental Business Operations at this location		Effective Date of Most Recent Transfer of Dental Business Ownership (If Applicable)	

REGULATORY EXEMPTIONS CLAIMED

Based on any of the following criteria, a dental business may qualify for an exemption from the requirements of 40 CFR Part 441⁽¹⁾. **Mark the check box AND include your initials** to certify each exemption claimed. **If claiming an exemption, skip to the Compliance Certification section.**

- “The dental business identified **exclusively practices** one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics.”
_____ (initials).
- “The dental business identified conducts **all dental services** from one or more **mobile units** (defined as a specialized mobile self-contained van, trailer or other equipment used in providing dentistry services at multiple locations).”
_____ (initials).
- “The dental business identified **collects all dental amalgam process wastewater for transfer and hauling** to a Centralized Waste Treatment facility as defined in 40 CFR Part 437.2⁽²⁾.”
_____ (initials).

(This means the facility does not have an amalgam separator and that all dental process wastewater that has been in contact with amalgam is collected and hauled off-site by a professional waste hauling company.)

- “The dental business identified **does NOT place or remove dental amalgam**, except in limited emergency or unplanned, unanticipated circumstances (according to the rules this means that, on average, less than 5% of the removal procedures involve dental amalgam, and that the business does not stock amalgam capsules or accept new patients with amalgam fillings).”
_____ (initials).

PROCESS INFORMATION

Description of Facility				
Total number of chairs:				
Total number of chairs in which dental amalgam may be removed and wastewater may be produced:				
Number of Amalgam Separators or Equivalent Devices installed:				
Amalgam Separator Information				
Manufacturer Name	Model	Year of Installation (Not most recent canister change)	Number of Chairs connected	Is Separator Certified Under ISO 11143 Standard ⁽³⁾ ?
				<input type="checkbox"/> Yes <input type="checkbox"/> No
				<input type="checkbox"/> Yes <input type="checkbox"/> No

Is a 3rd party service provider used in maintaining amalgam separators or equivalent devices? (this would include completing the required service checks, shipping, and replacement of canisters) Yes No

Name of 3 rd Party Service Provider				
3 rd Party Physical Address (Street Address must include Building and/or Suite ID)				
City:		State:		Zip:

3 rd Party Service Contact Name			
Phone:		Email:	

If a 3rd party service provider is **NOT** used, provide a brief description of in-house practices employed by the dental business to ensure proper inspection, operation and maintenance of these separators or devices in accordance with 40 CFR 441.30⁴ and 40 CFR 441.40⁵, including frequency of service checks, who is responsible, and how disposal of canisters will be handled:

Describe practices:

Mark the check box AND include your initials to certify **each** of the following statements:

- “The dental business identified uses amalgam separator(s) or equivalent device(s) that are designed, inspected, operated and maintained to meet the requirements specified in 40 CFR § 441.30⁽⁴⁾ or § 441.40⁽⁵⁾.”
_____ (initials).
- “The dental business identified is implementing Best Management Practices (BMPs) specified in 40 CFR § 441.30⁽⁴⁾ or § 441.4⁽⁵⁾, including the prohibition of the discharge of waste amalgam from chair-side traps, screens, vacuum pump filters, dental tools, cuspidors, or collection devices to the sewer system; and the prohibition of the use of oxidizing and acidic cleaning products, including but not limited to bleach, chlorine, iodine and peroxide that have a pH lower than 6 or greater than 8 on plumbing fixtures and lines that convey amalgam wastes.”
_____ (initials).

COMPLIANCE CERTIFICATION

Authorized Representative for Dental Business			
Identify an Authorized Representative for the Dental Business below. For a corporation, this must be a responsible corporate officer meeting the requirements of 40 CFR 403.12(l)(1) ⁽⁶⁾ . For partnerships or sole proprietorships, this must be a general partner or proprietor, respectively. For government agencies or institutional organizations, this must be the director or highest appointed official designated to oversee the business operations.			
The Authorized Representative, or Duly Authorized Representative as identified in accordance with 40 CFR 403.12(l) ⁽⁶⁾ , must sign this statement.			
<i>I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.</i>			
Name (printed):		Signature:	
Title:		Phone:	
Date:			

RETENTION PERIOD

In accordance with 40 CFR § 441.50(a)(5)⁽⁷⁾, as long as a Dental Facility subject to these regulations is in operation, or until ownership is transferred, the Dental facility or an agent or representative of the dental facility must maintain this One Time Compliance Report and make it available for inspection in either physical or electronic form.

Footnotes:

1. A full copy of 40 CFR Part 441 is provided on pages 5 - 9.
2. 40 CFR Part 437.2 "General definitions" (c) *Centralized waste treatment (CWT) facility* means any facility that treats (for disposal, recycling or recover 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."
3. A full copy of the ISO 11143 Standard can be found at the following link:
<https://www.sis.se/api/document/preview/909960/>
4. 40 CFR Part 441.30 can be found on pages 6 - 8.
5. 40 CFR Part 441.40 can be found on page 8.
6. 40 CFR Part 403.12(l): "*Signatory requirements for Industrial User reports*. The reports required... shall be signed as follows: 1) By a responsible corporate officer, if the Industrial User submitting the reports required... is a corporation. For the purpose of this paragraph, a responsible corporate officer means: i) a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or ii) The manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; can ensure that the necessary systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures."
7. 40 CFR Part 441.50(a)(5) can be found on page 9.

Title 40 of the Code of Federal Regulations Part 441

§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.