


AMALGAM SEPARATORS
FIVE THINGS TO KNOW

DISCLAIMER

- KAREN GREGORY RN IS AN EMPLOYEE OF TOTAL MEDICAL COMPLIANCE.
- KAREN GREGORY IS A HURFIEDY KEY OPINION LEADER, A CONSULTANT FOR SCICAN AND SERVES ON THE OSAP BOARD OF DIRECTORS.



OBJECTIVES

- DISCUSS THE ACTIONS REQUIRED BY THE RULE
- RECALL EXEMPTIONS TO THE REGULATION
- DISCUSS RECORD KEEPING REQUIREMENTS

FIVE THINGS TO KNOW

- WHY THIS RULE IS NECESSARY
- REQUIRED ACTIONS
- WHO IS IMPACTED
- WHEN PRACTICES MUST COMPLY
- DOCUMENTATION REQUIREMENTS



DEFINITIONS

- AMALGAM – ELEMENTAL MERCURY AND OTHER METALS
- MERCURY RELEASES VAPOR - ABSORBED BY THE LUNGS
- TWO NEARLY EQUAL PARTS:
 - LIQUID MERCURY – BOND THE POWDER COMPONENTS
 - POWDER - SILVER, TIN, COPPER, ZINC, OTHER METALS
- CONTACT – CONTACT WITH THE PATIENT
 - EXTRACTED TEETH, CARVING SCRAP, CHAIR SIDE TRAP
- POTW – PUBLICALLY OWNED TREATMENT WORKS

WHY IS THIS RULE NECESSARY?

- MAIN SOURCE OF MERCURY DISCHARGES TO POTWS
- EPA - 103,000 OFFICES USE/REMOVE
- DISCHARGE APPROXIMATELY 5.1 TONS OF MERCURY ANNUALLY

Source: EPA

ENVIRONMENT

- WASTE ENTER THE WASTEWATER STREAM - POTWS
- POTWS REMOVE AROUND A 90% OF AMALGAM WASTE
- WASTE BECOMES PART OF THE POTW'S SEWAGE SLUDGE DISPOSAL
 - **LANDFILLS** - RELEASED INTO THE GROUND WATER OR AIR
 - **INCINERATION** - MAY BE EMITTED TO THE AIR.
 - **APPLY SLUDGE TO AGRICULTURAL LAND AS FERTILIZER** - MAY EVAPORATE TO THE ATMOSPHERE

FDA – AMALGAM FILLINGS


- CONCERN WITH EVEN THE LOW LEVELS OF MERCURY VAPOR ASSOCIATED WITH AMALGAM FILLINGS
- CREDIBLE SCIENTIFIC EVIDENCE DOES **NOT** ESTABLISH AN ASSOCIATION BETWEEN AMALGAM USE AND ADVERSE HEALTH EFFECTS
- FDA CONSIDERS AMALGAM FILLINGS SAFE FOR ADULTS AND CHILDREN AGES 6 AND ABOVE

**EPA
USE OF AMALGAM SEPARATORS**

- **EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR THE DENTAL CATEGORY**
- DECEMBER 2016 – RULE PUBLISHED
- JANUARY 20, 2017 – REGULATION FROZEN BY NEW ADMINISTRATION
- REINSTATED AND EFFECTIVE DATE - JULY 14, 2017
- COMPLIANCE DATE FOR MOST DENTIST - JULY 14, 2020

ULTIMATE GOAL

THE INSTALLATION OF AMALGAM SEPARATORS, WHICH CATCH AND HOLD THE EXCESS AMALGAM WASTE, CAN FURTHER REDUCE DISCHARGES TO WASTEWATER



CAPTURING AMALGAM

- SEDIMENTATION, FILTRATION, CENTRIFUGATION, OR A COMBINATION.⁶
- ION EXCHANGE TECHNOLOGY TO REMOVE MERCURY FROM WASTEWATER.⁶



AMALGAM WASTE DEFINED

- SCRAP AMALGAM
- CHAIR-SIDE TRAP FILTERS
- VACUUM PUMP FILTERS
- SALIVA EJECTORS
- USED AMALGAM CAPSULES
- EXTRACTED TEETH WITH AMALGAM RESTORATIONS
- WASTE ITEMS CONTAMINATED WITH AMALGAM

Amalgam Separators and Waste Best Management - ADA

EXEMPTIONS

- ORAL PATHOLOGY
- ORAL AND MAXILLOFACIAL RADIOLOGY AND SURGERY ORAL
- ORTHODONTICS
- PERIODONTICS
- PROSTHODONTICS
- DO NOT PLACE AMALGAM AND ONLY REMOVE IN UNPLANNED/EMERGENCY SITUATIONS (LESS THAN 5%)
- MOBILE DENTAL UNITS
- SEPARATORS IN PLACE: GRANDFATHERED FOR 10 YEARS

EXISTING PRACTICES

- NO LATER THAN JULY 14, 2020 INSTALLATION, OPERATION, AND MAINTENANCE OF ONE OR MORE AMALGAM SEPARATORS:
 - ANSI/ADA SPECIFICATION 108 (2009) WITH TECHNICAL ADDENDUM (2011) OR
 - (ISO) 11143 STANDARD (2008)
 - AT LEAST A 95% REMOVAL EFFICIENCY
 - SIZED TO ACCOMMODATE THE MAXIMUM DISCHARGE RATE OF AMALGAM PROCESS WASTEWATER

AMALGAM SEPARATORS

- INSPECTED BASED ON MANUFACTURER'S INSTRUCTIONS
 - PROPER OPERATION AND MAINTENANCE
 - CONFIRM ASTEWATER IS FLOWING THROUGH THE AMALGAM RETAINING PORTION OF THE SEPARATOR(S)
- NOT FUNCTIONING PROPERLY, MUST BE REPAIRED OR REPLACED
 - ASAP - NO LATER THAN 10 BUSINESS DAYS
- REPLACED BASED ON MANUFACTURER'S SCHEDULE OR WHEN FULL

BEST MANAGEMENT PRACTICES

- WASTE AMALGAM INCLUDING AMALGAM
 - CHAIR-SIDE TRAPS
 - VACUUM PUMP FILTERS
 - DENTAL TOOLS
 - CUSPIDORS
 - COLLECTION DEVICES
- DENTAL UNIT WATER LINES (SUCTION) THAT DISCHARGE AMALGAM WASTEWATER TO A POTW
 - MUST NOT BE CLEANED WITH OXIDIZING OR ACIDIC CLEANERS - BLEACH, CHLORINE, IODINE AND PEROXIDE (PH LOWER THAN 6 OR GREATER THAN 8)

DENTAL UNIT WATERLINE

- 40 CFR 441.30(B)(2), THE TERM DENTAL UNIT WATER LINES IS LIMITED TO WASTE WATER LINES.
- DOES NOT INCLUDE WATER LINES THAT SUPPLY WATER TO HANDPIECES, ULTRASONIC SCALERS, AIR/WATER SYRINGES, ETC.
- NO RESTRICTIONS ON PRODUCTS FOR USE IN CONTROLLING CONTAMINATION AND/OR MICROBIAL BIOFILM.

ADA - BEST PRACTICES

- PRECAPSULATED AMALGAM ALLOY NOT BULK ELEMENTAL MERCURY
- USE APPROPRIATE PPE –BLOODBORNE PATHOGENS
- STORE AMALGAM WASTE IN A COVERED PLASTIC CONTAINER, INCLUDING THE BIOHAZARD SYMBOL
- CONTACT RECYCLER OR ANY SPECIFIC STORAGE INSTRUCTIONS
- DON'T FLUSH AMALGAM WASTE DOWN THE DRAIN
- DON'T USE BLEACH PRODUCTS FOR FLUSHING EVACUATION LINES

NEW PRACTICES

- AS OF JULY 14, 2017, ANY NEW SOURCE MUST COMPLY.
- OPENED ON OR AFTER THIS DATE MUST COMPLY.



ONE TIME COMPLIANCE REPORT

- EXISTING SOURCES
 - REPORT MUST BE SUBMITTED TO THE CONTROL AUTHORITY NO LATER THAN OCTOBER 12, 2020 OR 90 DAYS AFTER TRANSFER OF OWNERSHIP
- NEW SOURCES
 - NO LATER THAN 90 DAYS FOLLOWING THE INTRODUCTION OF WASTEWATER INTO THE POTW
- SIGNATURE AND CERTIFICATION
 - CORPORATE OFFICER, A GENERAL PARTNER OR PROPRIETOR, OR A DULY AUTHORIZED REPRESENTATIVE
- MUST MAINTAIN A COPY OF THIS REPORT WHILE IN OPERATION OR UNTIL OWNERSHIP IS TRANSFERRED

CONTROL AUTHORITY

- EITHER A LOCAL WASTEWATER UTILITY, A STATE ENVIRONMENTAL AGENCY, OR A U.S. EPA REGIONAL OFFICE.
- ALABAMA, CONNECTICUT, MISSISSIPPI, NEBRASKA OR VERMONT
 - YOUR CONTROL AUTHORITY IS YOUR **STATE AGENCY**.
 - STATE AGENCY CONTACTS
- ALL OTHER STATES
 - CONTACT YOUR EPA REGIONAL OFFICE, YOUR LOCAL WASTEWATER UTILITY, OR YOUR STATE AGENCY PRETREATMENT COORDINATOR PRETREATMENT PROGRAM CONTACTS

Contact Us: National Pretreatment Program

Headquarters Contacts
Regional Contacts
State Agency Contacts

State Agency Contacts

A B C D E F G H I K L M N O P R S T U V W

Alabama

Alabama Department of Environmental Management
 Samantha P. Sims (ssims@adem.state.al.us) (334) 394-4364
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DETERMINING YOUR CONTACT JURISDICTION, PLEASE SEE EPA'S WEBSITE: www.epa.gov/epaospr/epaospr/naaqs/naaqs.html

General Information

Name of Facility		
Physical Address of Dental Facility		
City:	State:	Zip:
Mailing Address		
City:	State:	Zip:
Facility Contact		
Phone:	Email:	
Names of Owner(s):		
Names of Operator(s) if different from Owner(s):		

Applicability: Please Select One of the Following


This facility is a dental discharger subject to this rule (40 CFR Part 441) and it places or removes dental amalgam.

DOCUMENTATION

- HAVE AVAILABLE FOR INSPECTION IN EITHER PHYSICAL OR ELECTRONIC FORM, FOR A MINIMUM OF THREE YEARS:
 - DATE, PERSON(S) CONDUCTING THE INSPECTION, AND RESULTS OF EACH INSPECTION OF THE SEPARATOR(S) OR EQUIVALENT DEVICE(S), AND A SUMMARY OF FOLLOW-UP ACTIONS
 - DATE OF CONTAINER OR EQUIVALENT CONTAINER REPLACEMENT
 - DATES THAT COLLECTED AMALGAM IS PICKED UP OR SHIPPED FOR PROPER DISPOSAL
 - NAME OF THE PERMITTED OR LICENSED TREATMENT, STORAGE OR DISPOSAL FACILITY RECEIVING THE CONTAINERS.
 - DOCUMENTATION OF DATE FOR ANY REPAIR OR REPLACEMENT, PERSON(S) MAKING THE REPAIR OR REPLACEMENT, AND A DESCRIPTION OF THE REPAIR OR REPLACEMENT

AND.....

- A COPY OF THE OWNERS MANUAL




DECISION TIME



RECYCLER QUESTIONS
ADA BEST PRACTICES

- WHAT TYPE OF WASTE IS ACCEPTED? FILTERS FROM SEPARATORS? EXTRACTED TEETH?
- DOES THE WASTE NEED TO BE DISINFECTED?
- PICK UP OR MAIL OFF OPTIONS?
- IS PACKAGING PROVIDED? IF NOT, INSTRUCTIONS FOR APPROPRIATE PACKAGING OR STORAGE?
- WHAT TYPE OF DOCUMENTATION WILL BE PROVIDED?
- WILL YOU PAY FOR NON-CONTACT AMALGAM?



Thank You

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REFERENCES

- AMERICAN DENTAL ASSOCIATION. AMALGAM WASTE BROCHURE. ACCESSED AUGUST 30, 2017
- AMERICAN DENTAL ASSOCIATION. BEST MANAGEMENT PRACTICES FOR AMALGAM WASTE. OCTOBER 2007. ACCESSED AUGUST 30, 2017
- AMERICAN DENTAL ASSOCIATION. AMALGAM SEPARATORS AND WASTE BEST MANAGEMENT. ACCESSED AUGUST 30, 2017
- FDA. ABOUT DENTAL AMALGAM FILLINGS. ACCESSED AUGUST 30, 2017.
- FEDERAL REGISTER. EFFLUENT LIMITATIONS GUIDELINES AND STANDARDS FOR THE DENTAL CATEGORY. ACCESSED AUGUST 31, 2017.
- U.S. ENVIRONMENTAL PROTECTION AGENCY. MERCURY IN DENTAL AMALGAM. ACCESSED AUGUST 30, 2017.

SAMPLE
ONE-TIME COMPLIANCE REPORT FOR DENTAL DISCHARGERS
to Comply with 40 CFR 441.50
Effluent Limitations Guidelines and Standards for the Dental Office Category

Instructions:

The following is a sample form that contains the minimum information dental facilities must submit in a one-time compliance report as required by the Effluent Limitations Guidelines and Standards for the Dental Office Category (“Dental Amalgam Rule”). Some dental facilities are not required to submit a one-time compliance report. See [the applicability section \(§ 441.10\)](#) to determine if your facility is required to submit a one-time compliance report.

Note to dental facilities: Do not fill out and submit this form unless directed to do so by your Control Authority. Please contact your Control Authority to determine what form to use. Your Control Authority may be your wastewater utility, your state wastewater agency, or the U.S. EPA Regional Office. For assistance in determining your Control Authority, please see EPA’s website: www.epa.gov/eg/dental-effluent-guidelines.

General Information

Name of Facility					
Physical Address of Dental Facility					
City:		State:		Zip:	
Mailing Address					
City:		State:		Zip:	
Facility Contact					
Phone:		Email:			
Names of Owner(s):					
Names of Operator(s) if different from Owner(s):					

Applicability: Please Select One of the Following

<input type="checkbox"/>	This facility is a dental discharger subject to this rule (40 CFR Part 441) and it places or removes dental amalgam. <i>Complete sections A, B, C, D, and E</i>
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<input type="checkbox"/>	This facility is a dental discharger subject to this rule and (1) it does not place dental amalgam, and (2) it does not remove amalgam except in limited emergency or unplanned, unanticipated circumstances. <i>Complete section E only</i>
(Also, select if applicable) Transfer of Ownership (§ 441.50(a)(4))	
<input type="checkbox"/>	This facility is a dental discharger subject to this rule (40 CFR Part 441), and it has previously submitted a one-time compliance report. This facility is submitting a new One Time Compliance Report because of a transfer of ownership as required by § 441.50(a)(4) .

Section A

Description of Facility

Total number of chairs:		
Total number of chairs at which amalgam may be present in the resulting wastewater (i.e., chairs where amalgam may be placed or removed):		
Description of any amalgam separator(s) or equivalent device(s) currently operated:		
YES <input type="checkbox"/>	NO <input type="checkbox"/>	The facility discharged amalgam process wastewater prior to July 14th, 2017 under any ownership.

Section B

Description of Amalgam Separator or Equivalent Device

<input type="checkbox"/>	The dental facility has installed one or more ISO 11143 (or ANSI/ADA 108-2009) compliant amalgam separators (or equivalent devices) that captures all amalgam containing waste at the following number of chairs at which amalgam placement or removal may occur:	Chairs:
<input type="checkbox"/>	The dental facility installed prior to June 14, 2017 one or more existing amalgam separators that do not meet the requirements of § 441.30(a)(1)(i) and (ii) at the following number of chairs at which amalgam placement or removal may occur: I understand that such separators must be replaced with one or more amalgam separators (or equivalent devices) that meet the requirements of § 441.30(a)(1) or § 441.30(a)(2) , after their useful life has ended, and no later than June 14, 2027, whichever is sooner.	Chairs:
	Make	Model
		Year of installation
<input type="checkbox"/>	My facility operates an equivalent device.	

Make	Model	Year of installation	Average removal efficiency of equivalent device, as determined per § 441.30(a)(2)i- iii.

Section C

Design, Operation and Maintenance of Amalgam Separator/Equivalent Device

<input type="checkbox"/>	YES	I certify that the amalgam separator (or equivalent device) is designed and will be operated and maintained to meet the requirements in § 441.30 or § 441.40 .	
A third-party service provider is under contract with this facility to ensure proper operation and maintenance in accordance with § 441.30 or § 441.40 .			
<input type="checkbox"/>	YES	Name of third-party service provider (e.g. Company Name) that maintains the amalgam separator or equivalent device (if applicable):	
<input type="checkbox"/>	NO	If none, provide a description of the practices employed by the facility to ensure proper operation and maintenance in accordance with § 441.30 or § 441.40 .	
<i>Describe practices:</i>			

Section D

Best Management Practices (BMP) Certifications

<input type="checkbox"/>	The above named dental discharger is implementing the following BMPs as specified in § 441.30(b) or § 441.40 and will continue to do so.
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- 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 publicly owned treatment works (e.g., municipal sewage system).
- Dental unit water lines, chair-side traps, and vacuum lines that discharge amalgam process wastewater to a publicly owned treatment works (e.g., municipal sewage system) 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 (i.e. cleaners that may increase the dissolution of mercury).

Section E

Certification Statement

Per [§ 441.50\(a\)\(2\)](#), the One-Time Compliance Report must be signed and certified by a responsible corporate officer, a general partner or proprietor if the dental facility is a partnership or sole proprietorship, or a duly authorized representative in accordance with the requirements of [§ 403.12\(l\)](#).

“I am a responsible corporate officer, a general partner or proprietor (if the facility is a partnership or sole proprietorship), or a duly authorized representative in accordance with the requirements of § 403.12(l) of the above named dental facility, and 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.”

Authorized Representative Name (print name):			
Phone:		Email:	
Authorized Representative Signature		Date	

Retention Period; per [§ 441.50\(a\)\(5\)](#)

As long as a Dental facility subject to this part 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.