

Dental Amalgam Rule 40 CFR 441

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PHOEBE LOW

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List of Acronyms

- ▶ **ADA** – American Dental Association
- ▶ **ANSI** – American Nation Standards Institute
- ▶ **BMP** – Best Management Practices
- ▶ **CIU** – Categorical Industrial User
- ▶ **ISO** – International Organization for Standardization
 - ▶ Current ISO standard for amalgam separators is ISO 11143
- ▶ **OTC** – One-Time Compliance (report)
- ▶ **POTW** – Publicly Owned Treatment Works
- ▶ **SIU** – Significant Industrial User

GOALS for this Presentation

- ▶ WHY is this important?
- ▶ WHO needs to do something?
 - ▶ Which POTWs?
 - ▶ Which Dental Offices?
- ▶ WHAT are these requirements?
- ▶ WHEN are these requirements due?
- ▶ WHERE should you start?

Note – I'm only covering the minimum requirements according to the new rule. You may apply stricter rules/deadlines, but you cannot relax them.



Purpose of the Rule

- ▶ Reduce the discharges of mercury and other metals from dental offices into POTWs.
- ▶ Keep paperwork at a minimum while reducing discharges.



WHY?

WHY MERCURY?

WHY DENTAL OFFICES?

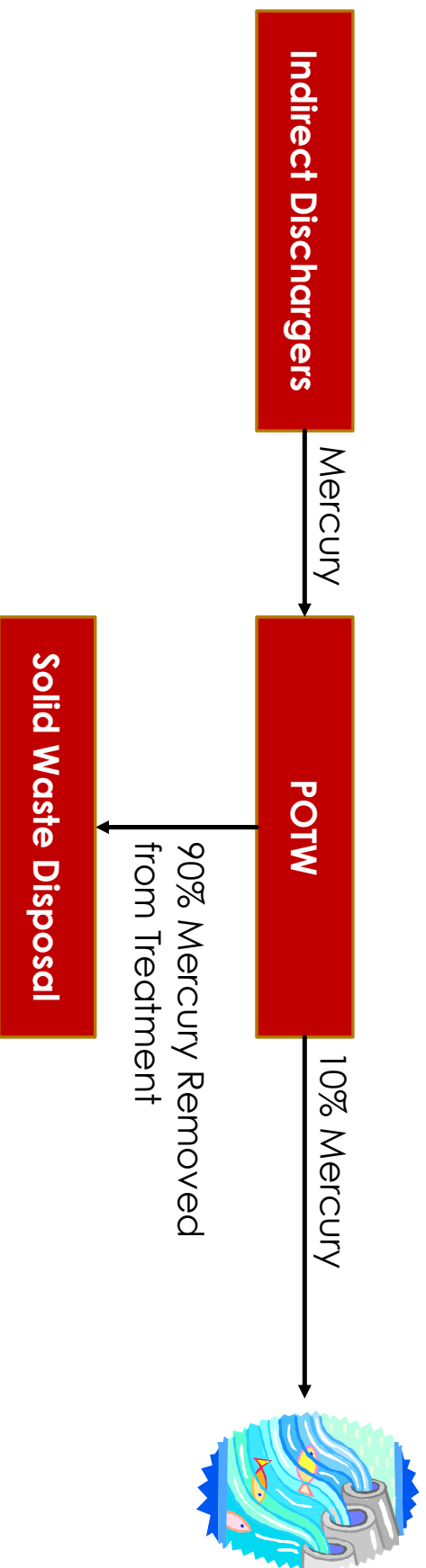
WHY AMALGAM?

**WHY DOES THIS RULE
MATTER?**

WHY Mercury?

- ▶ Mercury + Bacteria = Methylmercury
- ▶ Methylmercury = highly toxic form of mercury that bioaccumulates in fish and shellfish
- ▶ In the U.S., consumption of fish and shellfish is the main source of methylmercury exposure to humans

WHY Mercury? (continued)



- ▶ Easier to remove mercury before reaching POTWs.
Legislature has to apply to specific industry → dental offices.

WHY Dental Offices?

- ▶ Dental offices are the main source of mercury discharges to POTWs.
- ▶ A 2005 study funded by the ADA estimated that dental offices contributed 50% of mercury entering POTWs. [1][2]

[1] Vandeven, J., and S. McGinnis. 2005. An Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States. *Water, Air and Soil Pollution*. 164:349-366.

[2] Larry Walker Associates. 2002. *Mercury Source Control and Pollution Prevention Program Evaluation*. Prepared for Association for Metropolitan Sewerage Agencies. AMSA. March (Updated July).

WHY Amalgam?

- ▶ Amalgam = Dental offices' main source of mercury discharged to POTWs
- ▶ Discharged when dentists...
 - ▶ Remove amalgam fillings from cavities
 - ▶ Place amalgam (excess amalgam)
- ▶ Largest amalgam contributor = Removal of amalgam fillings^[1]
- ▶ EPA estimates that a single-chair dental office would remove amalgam 183 times per year.^[2]

[1] U.S. EPA. 2016c. Dental Office Cost Calculations. MS Excel® File. Office of Water. Washington, D.C. December.

[2] U.S. EPA. 2016d. *Limited Emergency Removals of Dental Amalgam*. Memorandum to the Public Record for the Dental Category Final Rule. Office of Water. Washington, DC. August 6.

WHY Amalgam? (continued)

- ▶ But isn't the use of Dental Amalgam in decline?
 - ▶ Alternative materials (composite resins and glass ionomers)
 - ▶ Steadily decreasing since late 1970s
 - ▶ Placement of dental amalgam will only decrease by half within the next 25 years
- ▶ EPA estimates that dental waste will discharge **~2 tons of mercury to POTWS by 2040**

WHY Amalgam? (continued)

- ▶ Currently, EPA estimates that waste dental amalgam contributes to the POTWs in USA:
- ▶ **5.1 tons of mercury**
- ▶ Additional 5.3 tons of other metals

Pollutant	% of Amalgam by Weight ^[1]
Mercury	49
Silver	35
Tin	9
Copper	6
Zinc	1
Indium	Trace
Palladium	Trace

[1] Massachusetts Water Resources Authority. 2001. Amalgam Composition in Typical Dental Fillings (figure).

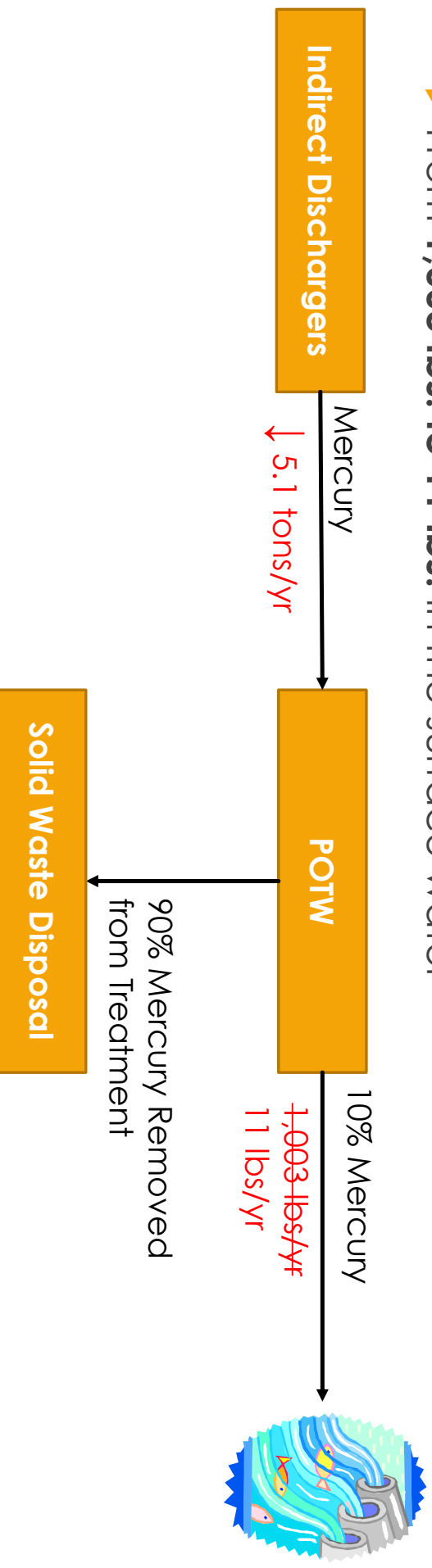
WHY Does this Rule Matter?

- ▶ *Before the Rule* – Only 12 states and at least 18 localities had established mandatory programs to reduce discharges of mercury to POTWs.
- ▶ These programs and outreach from American Dental Association (ADA)
 - ~40% of dentists subject to this rule already have installed amalgam separators.^[1]

[1] U.S. EPA. 2016a. Dental Office Cost Calculations. MS Excel® file. Office of Water. Washington, DC. December.

WHY Does this Rule Matter? (continued)

- ▶ Reduction of mercury → human health and ecological benefit
- ▶ Nationwide, EPA expects this rule to reduce amalgam mercury
 - ▶ By **5.1 tons/year** from POTWs' headworks
 - ▶ From **1,003 lbs. to 11 lbs.** in the surface water



WHO?

**WHICH POTWS ARE
AFFECTED?**

WHICH POTWs are Affected?

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Does POTW have Approved
Pretreatment Program?

YES = AFFECTED

POTW Enforces Dental
Amalgam Rule

NO = NOT Affected

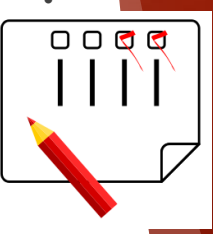
POTW Does NOT Enforce
Dental Amalgam Rule

Ohio EPA Enforces for POTW

What Should POTWs with Approved Programs Do?

**NOTE: POTWS MAY ENFORCE
MORE STRINGENT
REQUIREMENTS THAN THOSE IN
THE RULE.**

WHAT is Required of Approved POTWs?



- ▶ **1 – Create a list of dental dischargers that are applicable to the rule.**
- ▶ 2 – Develop a report for the dentists to fill out (One-Time Compliance Report).
- ▶ 3 – Make sure that dentists submit the form by the deadlines.
- ▶ 4 – Make sure all dentists that place/remove amalgam install an approved amalgam separator by the deadline.
- ▶ 5 – Monitor for new dental dischargers and make sure they comply with the rule.
- ▶ 6 – Maintain records.

LIST

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WHICH Dental Offices Count Towards the Rule (40 CFR 441.10)?

- ▶ Dental Offices EXCEPT for those listed in Slides 19-20 where the practice of dentistry is performed
 - ▶ Large institutions (dental schools and clinics)
 - ▶ Permanent or temporary offices
 - ▶ Home offices
 - ▶ Dental offices owned by federal, state, or local governments (including military bases)
- ▶ NOTE: Applicable Dental Offices are NOT considered CIUs or SIUs. They are just regular IUs.

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WHICH Dental Offices Are NOT Affected? (no action needed from POTW)

- ▶ Dental offices where practice of dentistry is exclusively one or more of the following dental specialties:
 - ▶ Oral pathology
 - ▶ Oral and maxillofacial radiology/surgery
 - ▶ Orthodontics
 - ▶ Periodontics
 - ▶ Prosthodontics
- ▶ Note: These specialties are not expected to engage in the practice of amalgam restorations/removals
- ▶ (list continues on next slide)

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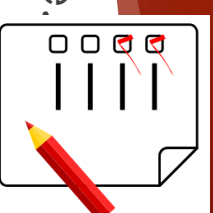
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WHICH Dental Offices Are NOT Affected? (continued)

- ▶ Dental offices discharging directly to waters of the state
- ▶ Dental wastewater from mobile units
- ▶ Dental wastewater to Centralized Waste Treatment Facility
- ▶ POTW doesn't have to do anything with these offices.
- ▶ These offices don't have to submit anything.



WHAT is Required of Approved POTWs?



- ▶ 1 – Create a list of dental dischargers that are applicable to the rule.
- ▶ **2 – Develop a report for the dentists to fill out (One-Time Compliance Report).**
- ▶ 3 – Make sure that dentists submit the form by the deadlines.
- ▶ 4 – Make sure all dentists that place/remove amalgam install an approved amalgam separator by the deadline.
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One-Time Compliance Report

- ▶ What needs to be in the OTC Report?
 - ▶ Different questions depending on whether dentist regularly places/removes amalgam.
 - ▶ Everything in 40 CFR 441.50.
 - ▶ Recommend that POTW develop this ASAP.



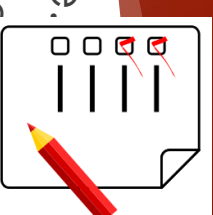
One-Time Compliance Report

- ▶ Developing the Report → Easy
- ▶ Ohio EPA's website has templates for you. 😊
 - Implementation of Dental Amalgam Standard (40 CFR 441) in Ohio fact sheet
 - Ohio EPA Amalgam Rule flow chart
 - 40 CFR Part 441: Dental Office Point Source Category
 - Dental Effluent Guidelines (U.S. EPA)
 - Ohio EPA One-Time Compliance Reports
 - Dental Dischargers with Amalgam Process Wastewater (Word) (PDF)
 - Dental Dischargers without Amalgam Process (Word) (PDF)
 - Approved Pretreatment Program POTWs — One-Time Compliance Report Templates
 - Dental Dischargers with Amalgam Process Wastewater (Word)
 - Dental Dischargers without Amalgam Process Wastewater (Word)
- ▶ Let Ohio EPA know if you want to remove questions/info from the form to make sure it won't affect your compliance.
 - ▶ I don't care if you add extra questions or give stricter requirements.

You need both forms for both situations



WHAT is Required of Approved POTWs?



- ▶ 1 – Create a list of dental dischargers that are applicable to the rule.
- ▶ 2 – Develop a report for the dentists to fill out (One-Time Compliance Report).
- ▶ **3 – Make sure that dentists submit the form by the deadlines.**
 - ▶ → **Distribute the form**
- ▶ 4 – Make sure all dentists that place/remove amalgam install an approved amalgam separator by the deadline.
- ▶ 5 – Monitor for new dental dischargers and make sure they comply with the rule.
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One-Time Compliance Report

- ▶ Deadlines
 - ▶ **October 12, 2020** – if discharge began on/before July 14, 2017
 - ▶ **Within 90 days of starting discharge** – if discharge began after July 14, 2017
 - ▶ Within 90 days of transferring ownership
 - ▶ Rule only requires each facility to fill it out *once* unless they transfer ownership.
 - ▶ Rule does not require them to notify you of starting/closing business or transferring ownership.



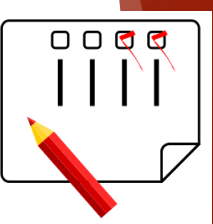
One-Time Compliance Report (continued)

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- ▶ Keep this report for your records.
- ▶ Do NOT send copies of OTC Reports to Ohio EPA.
- ▶ Do NOT tell dentists to send OTC Reports to Ohio EPA.



WHAT is Required of Approved POTWs?



- ▶ 1 – Create a list of dental dischargers that are applicable to the rule.
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- ▶ 3 – Make sure that dentists submit the form by the deadlines.
- ▶ **4 – Make sure all dentists that place/remove amalgam install an approved amalgam separator by the deadline.**
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What Are the General Requirements for Applicable Dental Offices?

- ▶ 1. Amalgam Separators (some exemptions apply)
 - ▶ A. Installation and Use
 - ▶ B. Operation and Maintenance
- ▶ 2. Two best management practices (BMPs)
 - ▶ A. Prohibit discharge of waste (scrap) amalgam
 - ▶ B. Prohibits use of line cleaners which may lead to dissolution of solid mercury when cleaning chair-side traps and vacuum lines
- ▶ 3. One-Time Compliance (OTC) Report

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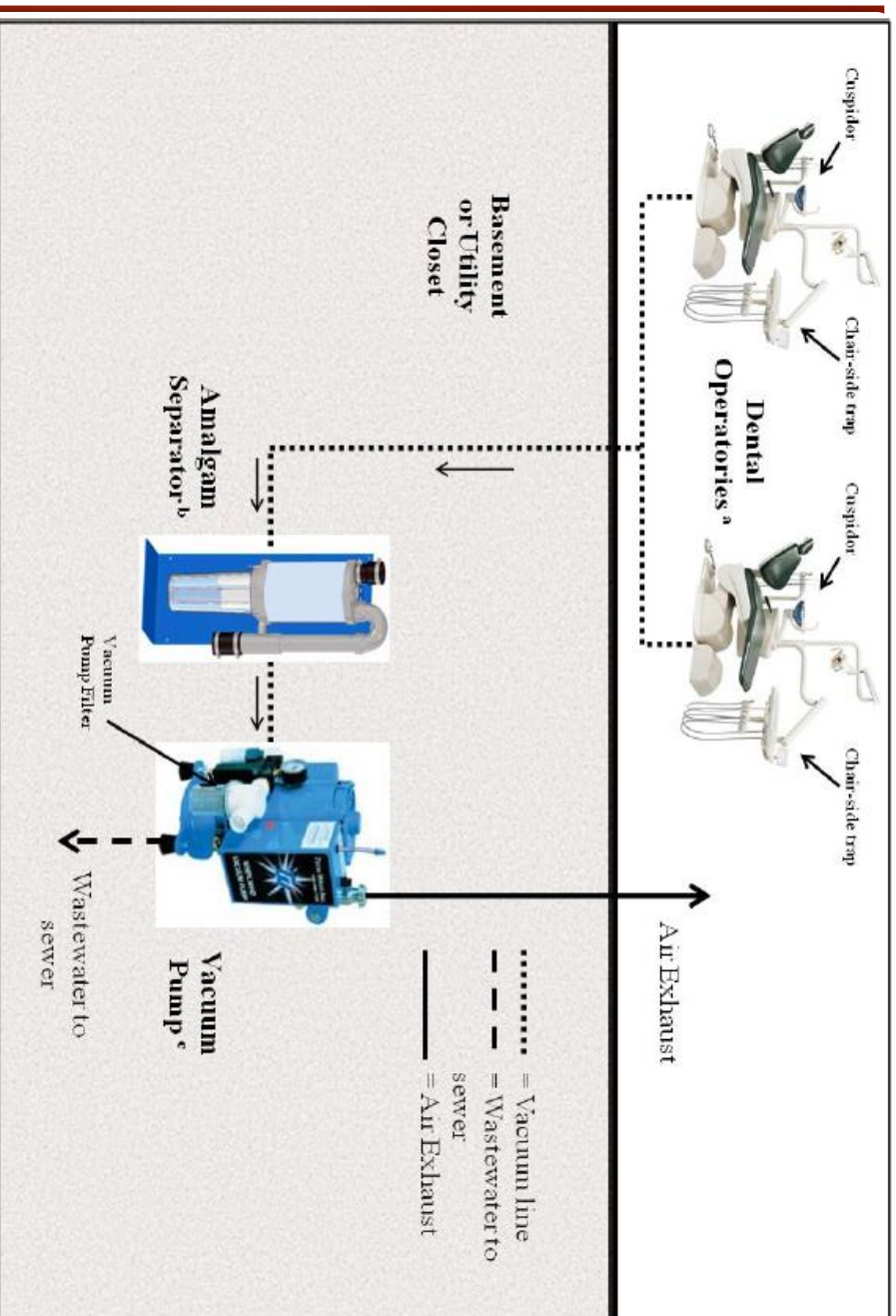
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Dental Office Requirements

1.A. Amalgam Separators – Installation & Use

- ▶ Amalgam separators remove amalgam particles from the wastewater through
 - ▶ Centrifugation
 - ▶ Sedimentation (most common)
 - ▶ Filtration
- ▶ OR a combination of any of these methods





Typical Amalgam Separator Plumbing Configuration

^a (Flight Dental Systems, 2006)

^b (Dental Equipment & Repair, 2008)

^c (Dental Classifieds, 2011)

Sources: Dube, 2010; McManus and Fan, 2003.

Technical and Economic Development Document for the Final
Effluent Limitations Guidelines and Standards for the Dental
Category. U.S. EPA. December 2016. Figure 5-1.

Without Amalgam Separator... Chair Side Trap

- ▶ Typical plumbing configuration
 - ▶ Chair-side trap for each chair
 - ▶ Central vacuum pump with a vacuum pump filter
- ▶ Combined, these systems remove ~78% of dental amalgam particles in wastewater stream^[1]

[1] Vandevern, J., and S. McGinnis. 2005. An Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States. *Water, Air and Soil Pollution*. 164:349-366.



Dental Office Requirements

1.A. Amalgam Separators – Installation & Use

- ▶ Appropriate Amalgam Separators Removal Rate
 - ▶ Median 99% removal efficiency of total dental solids.
 - ▶ 99% total mercury removal rate if existing chair-side traps and vacuum pump filters are used upstream. [1]

[1] Fan, P.L., H. Batchu, H.N. Chou, W. Gasparac, J. Sandrik, and D.M. Meyer. 2002. Laboratory Evaluation of Amalgam Separators. *Journal of American Medical Association*, 133:577-584.



Dental Office Requirements

1.A. Amalgam Separators – Installation & Use (continued)

- ▶ Appropriate Amalgam Separators must be compliant with
 - ▶ Both:
 - ▶ ANSI/ADA Standard No. 108 for Amalgam Separators
 - ▶ ISO 11143 Standard (2008)
 - ▶ OR Subsequent versions so long as that version requires at least a 95% removal efficiency



Dental Office Requirements

1.A. Amalgam Separators – Installation & Use (continued)

- ▶ Appropriate Amalgam Separators – Disposal of Waste
 - ▶ Several Amalgam Separator manufacturers offer services that facilitate the transport of waste amalgam to facilities that recycle the mercury
 - ▶ ADA posted a directory of amalgam recyclers (2012)
https://www.ada.org/~/media/ADA/Member%20Center/Files/Recyclers_Direct_4_02_12.pdf?la=en



Dental Office Requirements

1.B. Amalgam Separators – Operation & Maintenance

- ▶ EPA recommends an Amalgam Separator with a warning indicator
- ▶ Dental Office shall inspect separator in accordance with the manufacturer's operating manual
- ▶ Dental Office shall make repairs consistent with manufacturer instructions or replace the separator with a unit that meets ISO 11143 (or its equivalent)



WHEN Do Dental Offices Need to Install the Amalgam Separator?

- ▶ Deadlines to Install Amalgam Separator...

- ▶ If discharge began on/before July 14, 2017...

If Dental Office doesn't have Amalgam Separator	If There is Already an Amalgam Separator
July 14, 2020	June 14, 2027
When existing amalgam separator breaks down	
Which ever comes first	

- ▶ If discharge began after July 14, 2017 – Within 90 days of starting Discharge
- ▶ Within 90 days of transferring ownership



Who DOESN'T Need to Install an Amalgam Separator?

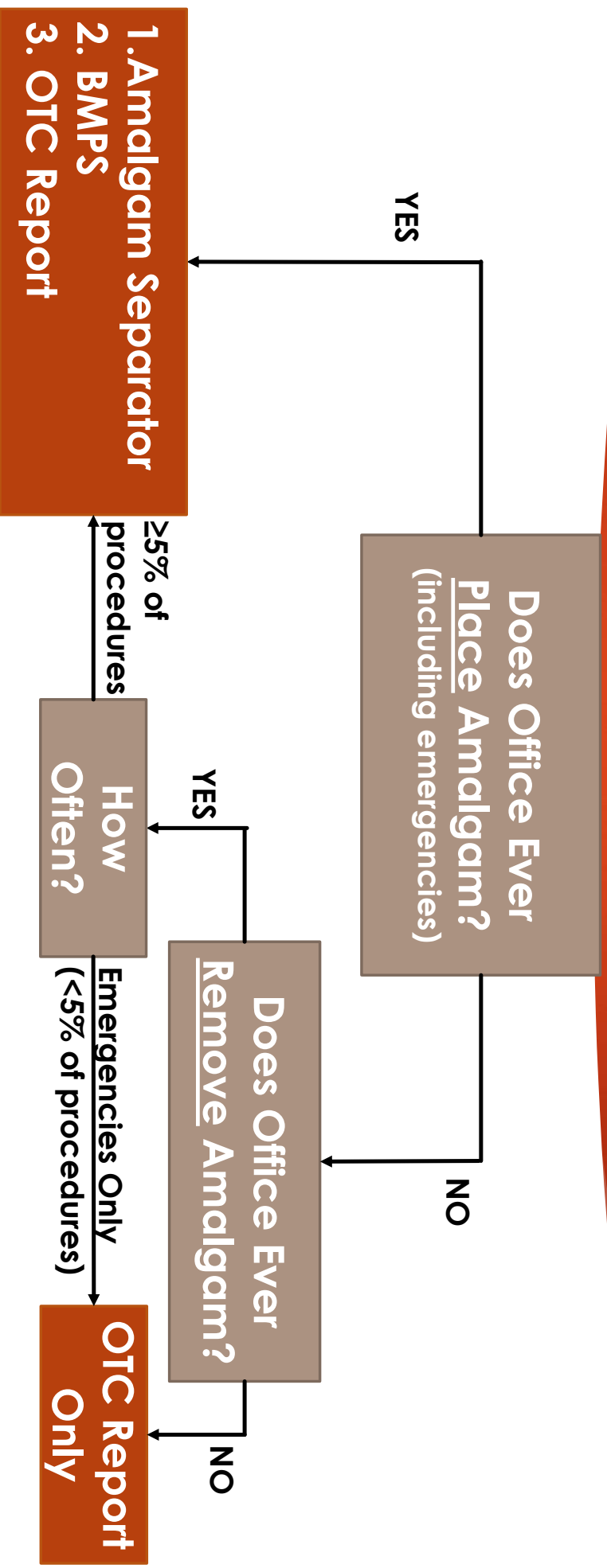
- ▶ Dental Offices that both:
 - ▶ 1. NEVER places dental amalgam
 - ▶ 2. DO NOT remove dental amalgam except in limited emergency or unplanned/unanticipated circumstances
- ▶ What Is an Emergency or Unplanned/Unanticipated Circumstance?
 - ▶ Recommended Threshold – Amalgam removal frequency is less than 5% of its procedures^[1]
 - ▶ On average, 5% of procedures approximates to 9 removals/year.

[1] U.S. EPA. 2016d. *Limited Emergency Removals of Dental Amalgam*. Memorandum to the Public Record for the Dental Category Final Rule. Office of Water. Washington, DC. August 6.



Dental Office Breakdown

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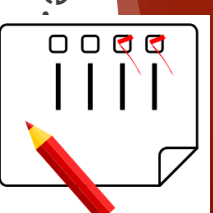


WHAT is required of Dental Offices? 2. Best Management Practices

- ▶ A. Prohibit flushing waste dental amalgam into any drain
- ▶ B. Prohibit Oxidizing Line Cleaners to clean dental unit water lines, chair side traps, or vacuum lines that lead to an amalgam separator
 - ▶ Cleaners can solubilize bound mercury captured in separator
→ increased mercury discharges
- ▶ Prohibits cleaners that have a pH lower than 6 or greater than 8.
 - ▶ Examples: bleach, chlorine, iodine and peroxide, etc.



WHAT is Required of Approved POTWs?



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- ▶ **5 – Monitor for new dental dischargers and make sure they comply with the rule.**
- ▶ 6 – Maintain records.

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How to Track Dental Office Numbers

(recommendations only)

Update

Update City's Ordinance to require dentists to notify POTW prior to starting business (need Ohio EPA approval first).

Check

Check with water treatment plant or local department for list of businesses.

Search

Search internet for dental offices in your city.

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How to Track Ownership Transfers

(recommendations only)

Resubmit

Require offices to resubmit OTC Report every five years

Notify
POTW

Add agreement in OTC Report that the dental office must notify the POTW [X] days prior to closing business or transferring ownership.

Inspect

Inspect dental offices every two years or so.

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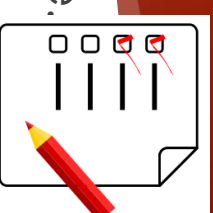
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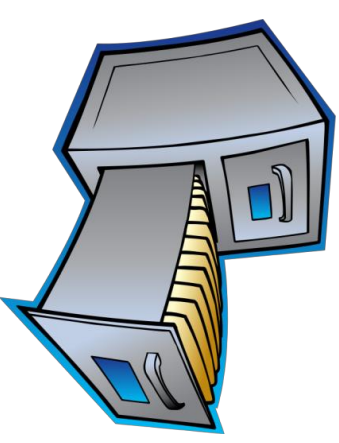
▶ 6 – **Maintain records.**



Recordkeeping

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- ▶ Same record requirements as other IUs.
- ▶ OTC Report until three years after the facility closes or transfers ownership.
- ▶ Three years for communications, inspection forms, sampling results, etc.
- ▶ Operator Manual must be on file at all times (not required by rule, but highly recommended)



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Approved Pretreatment Program POTWs' Responsibilities in a Nutshell!

Required

Develop OTC Report Form

Distribute OTC Report Form

Check that they install amalgam separator by deadline

Check that they all submit OTC Report by deadline

Take enforcement actions (if necessary)

NOT Required [1]

Sampling

Inspections

Permitting

[1] 40 CFR 441.10(b)

Approved Pretreatment Program POTWs in a Nutshell! (continued)

What should Approved Pretreatment Programs submit to Ohio EPA?

Submit to Ohio EPA	Do <u>NOT</u> submit to Ohio EPA
Annual Pretreatment Report - explain progress in narrative statement	Copies of completed OTC Reports
Mercury Variance Report (if applicable) - explain progress in narrative statement	Copies of letters/emails to dental dischargers

Miscellaneous Q&A

How Many Dental Offices Are There?

- ▶ Nationwide –134,397 U.S. dental offices owned or operated by 125,275 dental firms.
- ▶ Ohio – 4,201 dental establishments.

United States Census Bureau. Census Business Builder: Small Business Edition - 2.3. Accessed May 14, 2018.

How Many Dental Offices Will be Affected?

- ▶ ADA Estimates
 - ▶ 80% of the dental industry engages in general dentistry
 - ▶ 20% are specialty dentists exempted from the Rule
- ▶ For Ohio...
 - ▶ 80% of 4,201 dental offices = 3,360 dental offices will need to submit a
an OTC Report

How Many Dentists Need to Install Amalgam Separators?



- ▶ EPA estimates that of the dental offices subject to the Rule...
 - ▶ 40% already used amalgam separators prior to the Rule (June 2017)
 - ▶ 40% still have to install an amalgam separator
 - ▶ 20% do not need to install an amalgam separator^[1]
 - ▶ Do not place/remove amalgam
- ▶ If 40% of Ohio's applicable dental offices still need to install an amalgam separator, then 40% of 3,360 = 1,344 offices

[1] Pimpare, Justin. 2012. *Dentists Who Certify They Neither Place Nor Remove Amalgam*. Memorandum. U.S. EPA Region 1. 25 January.

What has Ohio EPA Done So Far?

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- ▶ Updated Website
 - ▶ Fact Sheet
 - ▶ OTC Report Forms
 - ▶ Diagram of Due Dates / Requirements
 - ▶ Templates of OTC Reports for Approved Programs
 - ▶ Emailed all Approved Pretreatment Programs about new rule
 - ▶ Starting to email all POTWs without approved programs - requesting list of dental users

Required	Not Required
Develop OTC Report Form 	Inspections
Distribute/Publish OTC Report Form 	Sampling
Check that they install amalgam removal device by deadline	Indirect Discharge Permits
Check that they all submit OTC Report by deadline	

Common Questions

- ▶ Do we have to update the city ordinance or enforcement response plan for this?
 - ▶ No – these dental offices are industrial users, not some special category... so they're already included in these documents.
- ▶ What if a POTW wants to make its own form from scratch?
 - ▶ You can do that, but send it to Ohio EPA to check that it follows the rules.
- ▶ What about dentists that don't discharge to a POTW with an approved pretreatment program?
 - ▶ That is something that Ohio EPA has to deal with.
- ▶ How much will it cost dentists?
 - ▶ The average annual cost for amalgam separators in 2016 was \$800.

Resources

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- ▶ Ohio EPA Dental Discharger Page:
<http://www.epa.ohio.gov/dsw/pretreatment/index.aspx#170115162-dental-effluent>
- ▶ List of Approved Pretreatment Programs:
<http://www.epa.ohio.gov/dsw/pretreatment/index.aspx>
- ▶ US EPA Dental Effluent Guidelines:
<https://www.epa.gov/eg/dental-effluent-guidelines#background>
- ▶ Federal Register:
<https://www.federalregister.gov/documents/2017/06/14/2017-12338/effluent-limitations-guidelines-and-standards-for-the-dental-category>

Questions?



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