This is a Pretreatment regulation, though it is not structured similarly to other Categorical Pretreatment Standards:
- A dental practice is not a Categorical Industrial User, unless designated as such by the Control Authority (approved community or DEP).
- A dental practice is not a Significant Industrial User, unless designated as such by the Control Authority (approved community or DEP).
- The General Pretreatment Regulation, 40 CFR Part 403 [CMR 06-096 Chapter 528 Pretreatment Program] is not affected.
- The “traditional suite of oversight requirements” is not required of the Control Authority.

The required compliance date will be 3 years from the date of final publication.

EXEMPTIONS  Part 441 does not apply to dental dischargers that do not discharge amalgam process wastewater to a POTW. This includes:
- Practices that discharge into septic systems.
- Practices that discharge into containment that is later pumped & shipped to Centralized Waste Treatment facilities.
- Part 441 does not apply to mobile dental units (vehicles or trailers).
- The following dental procedures are exempted, providing they are exclusively performed: Oral Pathology, Oral and Maxillofacial Radiology, Oral and Maxillofacial surgery, Orthodontics, Periodontics, and Prosthodontics.
- Dental offices that don’t place or remove amalgam, except in limited or unplanned emergency situations (defined as <5% of procedures, or 9 removals a year, whichever is lowest).

Dental offices that don’t place amalgam and don’t remove amalgam except in limited emergency or un-planned, un-anticipated circumstances are required to submit a one-time compliance certification report (signed and certified by the appropriate responsible party) to that effect, to the Control Authority. This report 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.

The EPA expects the practices to know the conditions requiring compliance (or exemption from it), and put a separator and BMPs in place if need be. The EPA also expects practices to not accept patients for non-exempt dental work who have amalgam fillings until they are prepared & in compliance with the Standard.

THREE FUNDAMENTAL BMPs  There are 3 fundamental BMPs that form the minimum acceptable requirements of practices covered under Part 441, for both Pretreatment Standards Existing Sources (PSES), and Pretreatment Standards New Sources (PSNS):
A separator must have, at a minimum, a **95% removal efficiency** and be sized to accommodate the maximum discharge rate of dental amalgam wastewater.

- The strict prohibition of the discharge or flushing of waste or “scrap” amalgam or related materials down any drain in the practice.
- The strict prohibition of the use of “oxidizing line cleaners”, defined as bleach, chlorine, [bromine?], iodine, and peroxide, or with a pH <6.0 or >8.0.

**NARRATIVE**

- A dental practice covered by this Standard is required to have the 3 fundamental BMPs in place, file a one-time compliance certification report (signed and certified by the appropriate responsible party) with the Control Authority that the dental discharge meets the requirements of the performance standard, conduct on-going operations and maintenance, and maintain associated records.
- One, some, or all of these requirements may be facilitated or carried out by a qualified 3rd party, such as a supplier or manufacturer. Practices electing to do so must indicate that in their compliance certification report. Practices that elect to carry out some or all of the requirements on their own must provide a satisfactory Operations and Maintenance Procedure.
- The on-time compliance report for dental dischargers subject to the Standard must include:
  - The facility name, physical address, mailing address, contact information, name of the operator(s), and owner(s);
  - A description of the operation at the dental facility, including the total number of chairs, number of chairs at which dental amalgam may be present in the resulting wastewater;
  - A description of any existing amalgam separator(s) or equivalent device(s) currently operated (to include at a minimum the make, model, and year of installation);
  - Certification that the amalgam separator(s) or equivalent device(s) is designed and will be operated in accordance with §441.30 or §441.40;
  - Certification that the dental discharger is implementing, at a minimum, the 3 fundamental BMPs;
  - The name of the 3rd party service provider, if applicable, or otherwise a brief description of the practices employed by the facility to ensure proper operation and maintenance.
  - This one-time compliance report must be retained for as long as the practice is in place, and made available for inspection in either an electronic or physical form.
- Dental dischargers or their agents must maintain the following records in either electronic or physical form for a minimum of 3 years:
  - Documentation of the date, person(s) conducting each separator inspection, the results, and a summary of follow-up actions if needed;
  - Documentation of amalgam containing container replacement, including the date;
  - Documentation of all dates that collected dental amalgam is picked up or shipped for proper disposal, and the name of the permitted or licensed treatment, storage, or disposal facility receiving the containers;
  - 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 & model);
  - Dischargers, or an agent of the dental discharger, must maintain and make available for inspection in either electronic or physical form the manufacturer’s operating manual for the current device.
- Existing separators may be operated for the useful life of the unit, or for 10 years from the date of installation, whichever comes first.
- At a minimum, all separators must be inspected according to manufacturer’s recommendation. Under some conditions of use, it may be necessary to inspect more frequently to prevent operation in bypass or beyond the point that filtration capacity is within compliance. The amalgam retaining unit (cartridge) must be replaced as per manufacturer specification or when filtration capacity is reached, whichever comes first. New installations should have a visual or auditory warning indicator for when the separator is nearly full or in bypass mode.
- Amalgam separator repairs or replacement must take place as soon as possible, but not later than 10 business days after discovery of an issue or malfunction.
- PSES; the one-time compliance report must be submitted not later than 90 days after the date of promulgation, or not later than 90 days after transfer of ownership.
- PSNS; the one-time compliance report must be submitted not later than 90 days following commencement of discharge.
- Electronic reporting is neither required nor precluded.
- There are provisions made for “alternative” device specifications for something other than the standard design amalgam separator.
- Though the explicit amalgam separator removal efficiency requirement in the Standard is >95%, the median efficiency of 2008 ISO – compliant devices is 99.3%.
- Dental amalgam is ≈ 49% mercury, 35% silver, 9% tin, 6% copper, and 1% tin.
- The standard explicitly indicates that there is much latitude in how a (delegated) state may run its program, but that it must do something reasonable ground-truth the process.