

EPA Amalgam Separator Frequently Asked Questions

Brief Summary

EPA Finalizes Amalgam Separator Rule

The Environmental Protection Agency (EPA) issued its [final rule](#) on amalgam separators. The rule requires most general dentists to install an amalgam separator to prevent mercury contained in dental amalgam from entering the air, water, and land. The rule is in effect on July 14, 2017; however, compliance for the majority of dentists is July 14, 2020. New dental offices established after July 14, 2017 and using dental amalgam, must comply with the rule immediately. Exemptions apply for some dental specialties and emergency removals of amalgam. The EPA has maintained the same [fact sheet](#) that was produced in December 2016.

EPA Final Amalgam Separator Final Rule Frequently Asked Questions (FAQs)

1. Is the final rule mandatory?

The final rule is mandatory but there are some exemptions depending on the specialty that you may practice.

2. What specialties are exempted?

General dentists will need to comply with this rule with rare exceptions. Oral pathologists, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, and prosthodontics are exempted from this rule.

3. What are the implementation dates?

The compliance date for existing dental businesses is July 14, 2020.

4. When do new businesses need to comply with the rule?

New businesses were subject to compliance with the rule immediately as of July 14, 2017.

5. If I don't place amalgam, do I still need a separator?

Most likely but, it depends on the volume of amalgam that your practice removes.

6. What is the threshold that EPA has determined whereby I don't need an amalgam separator?

On page 27163 of the 2017 Federal Register, the EPA did not take a bright line on the threshold issue. The rule states that dentists that do not place or remove amalgam except in "limited

circumstances” as a frequency of less than five percent of their procedures, would be exempt from further requirements of the rule. In that instance, the dentist would only need to file a one-time compliance report. According to data the EPA obtained, if a practice removes 9 cases or less of amalgam per year, the practice may not need to purchase an amalgam separator. With respect to the 9 cases, the EPA means the removal of amalgam from one tooth at each of those cases, not multiple teeth.

7. Do I need an amalgam separator for every chair?

Regarding the EPA final rule issued on June 14, 2017, a separate amalgam separator is not required for every chair.

The final rule does include cost analysis for multiple chair offices. However, the rule also contends that over time, amalgam may no longer be used in dental offices as usage is decreasing about 2% each year.

Whether you decide to furnish each chair with an amalgam separator likely depends on your practice. If you do not place amalgam and only remove amalgam sporadically, your need for chairs fitted with amalgam separators will likely be diminished. Some amalgam systems can be centrally located and service multiple chairs while other systems are designed for single chairs.

Some states may require an amalgam separator for each chair so be sure to check with your state regulatory authorities.

8. What states have amalgam separator regulations?

If you are practicing in certain states (CT, LA, ME, MA, MI, NH, NJ, NM, NY, RI, VT, WA), you may be subject to state requirements.

9. What localities have amalgam separator regulations?

Additionally, the rule cites 18 localities have mandatory dental amalgam reduction pretreatment programs (CA, CO, OH, and WI).

10. What are the costs associated with amalgam separators?

The EPA estimates that amalgam separators and affiliated services will cost dental offices on average approximately \$800 per office per year for one amalgam separator (in 2016 dollars). The charges are listed “per year” to average out the cost of an amalgam separator, as the devices may function for approximately a decade and then need to be exchanged. Prices will vary depending on how often the filter needs to be replaced, contract services such as removal and disposal, and other factors. As always, volume discounts will allow for more economical costs.

11. What does the rule mean by best management practices (BMPs)?

Best management practices:

1) Prohibit the discharge of waste (or scrap) into the water ways. Flushing waste amalgam from chair-side traps, screens, vacuum pump filters, dental tools, or collection devices into drains is prohibited;

2) Prohibit the use of line cleaners that may lead to the dissolution of solid mercury when cleaning chair-side traps and vacuum lines. Those cleaners include but are not limited to bleach chlorine, iodine and peroxide that have a pH lower than 6 or greater than 8.

12. What is the administrative burden of the rule?

Dentists need only fill out a one-time compliance report. Keep in mind that amalgam is a hazardous waste and dentists will need to keep records.

Dentists or an agent/representative of the amalgam separator must maintain and make available for inspection in either physical or electronic form, for a minimum of three years:

- 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.
- Documentation of amalgam retaining container or equivalent 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 amalgam retaining 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 and model).
- The manufacturer's operating manual for the current device either in physical or electronic form.

13. When and where was the final rule published?

The final rule was published in the Federal Register: Wednesday, June 14, 2017.

[Link to EPA Final Rule](#)

Link to [EPA Frequently Asked Questions \(FAQs\)](#)

14. What about amalgam discharges from mobile units?

Mobile units are not subject to this final rule as the EPA has insufficient data to make a determination.

15. I have an amalgam separator, do I need to replace it to comply with the rule?

The final rule allows dental offices to continue to operate existing amalgam separators for their lifetime or ten years (whichever comes first), as long as the dental discharger complies the other rule requirements including the specified BMPs, operation and maintenance, reporting and

recordkeeping requirements. Once the separator needs to be replaced or the ten-year period has ended, dental offices will need to replace the amalgam separator with one that meets the requirements of the final rule.

16. What if the dental practice changes ownership?

The new owner must submit a one-time compliance report that contains the required information.

17. What standards should the amalgam separator comply with?

The standard cited in the rule is the ISO 11143 2008 standard. Your dental supply company should be able to offer you options on amalgam separators that meet this ISO standard.

The final rule requires a documented amalgam separator inspection to ensure that the separator is performing properly.

18. What party conducts the inspection of the amalgam separator?

The answer will vary from state to state but the rule is not intended to be burdensome in terms of inspection or reporting requirements. Certain localities may also conduct inspections depending on your state and local regulations. The rule specifies that dentists need to demonstrate compliance with the best management practices and the performance standard for amalgam separators in a one-time report to their “control authority.”

19. Who is my Control Authority?

The EPA states that your Control Authority is either a local wastewater utility, a state environmental agency, or a U.S. EPA regional office. Dental offices in AL, CT, MS, NE, and VT should contact their state agency as their Control Authority.

20. Is there a sample One-Time Compliance Report for Dental Dischargers?

Yes. The EPA uses this sample form (Word):

[Sample One-Time Compliance Report for Dental Dischargers - EPA](#)

Be sure to check with your Control Authority for the appropriate form.

For additional questions, please contact practice@agd.org.