

**DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
DIRECTOR'S OFFICE  
DENTISTRY - GENERAL RULES**

**PART 8. DENTAL AMALGAM**

**R 338.11801 Definitions.**

Rule 1801. (1) As used in these rules:

- (a) "Amalgam separator" means a device designed to remove dental amalgam waste particles from dental office wastewater.
- (b) "Code" means 1978 PA 368, MCL 333.1101 to 333.25211.
- (c) "Dental amalgam" means a mixture of mercury and other metals used as a dental restorative material.
- (d) "Dental amalgam waste" means waste from a dental office containing any of the following:
  - (i) Contact amalgam waste, which means dental amalgam that has been in contact with the patient including, but not limited to, extracted teeth with dental amalgam restorations; carving scrap collected at chair-side; and dental amalgam captured by chairside traps, vacuum pump filters, amalgam separators, or other dental amalgam capture devices.
  - (ii) Non-contact amalgam scrap, which means dental amalgam that has not been in contact with the patient including, but not limited to, excess dental amalgam mix remaining at the end of a dental procedure.
  - (iii) Empty amalgam capsules, which means individually dosed containers left over after mixing precapsulated dental amalgam.
  - (iv) Dental amalgam that may have accumulated in the plumbing system or that is found in other areas of a dental office.
- (e) "Dentist," for the purposes of these rules, means an individual licensed under section 16611 of the code who uses or removes dental amalgam or who owns or operates a dental office that generates dental amalgam waste.
- (f) "Department" means the department of licensing and regulatory affairs.
- (g) "Discharge" means the release of any dental amalgam waste into the environment. This includes any releases to land, ground or surface waters, septic systems, or wastewater treatment systems.
- (h) "Holding tank" means a closed, watertight, sealed structure designed and used to receive and store wastewater. Holding tanks are designed and constructed for ultimate disposal of collected wastewater at another site.

(2) Terms defined in the code have the same meanings when used in these rules.

**R 338.11811 Amalgam separator; installation and operation; requirements.**

Rule 1811. (1) On or before December 31, 2013, a dentist shall install, or shall have installed, an amalgam separator on each wastewater drain in his or her dental office that is used to discharge dental amalgam waste. In addition to meeting the requirements of the code and these rules, a dentist who is required to install an amalgam separator shall comply with all of the following:

- (a) Install an amalgam separator that meets the requirements of R 338.11813.
  - (b) Install, operate, and maintain the amalgam separator according to the manufacturer's instructions.
  - (c) Ensure the installed amalgam separator is properly sized to accommodate maximum dental amalgam wastewater flow rates at the dental office. The maximum allowable flow rate through an amalgam separator at a dental office shall not exceed the maximum flow rate capacity at which the amalgam separator was tested under R 338.11813(1)(a).
  - (d) Ensure that all wastewater from the dental office containing dental amalgam waste passes through an installed and properly functioning and maintained amalgam separator before being discharged.
- (2) Subrule (1) of this rule shall not apply to any of the following:
- (a) Oral and maxillofacial surgeons.
  - (b) Oral and maxillofacial radiologists.
  - (c) Oral pathologists.
  - (d) Orthodontists.
  - (e) Periodontists.
  - (f) Dentists while providing services in a dental school, in a hospital, or through a local health department.
  - (g) Dentists who install and use a holding tank and do not discharge amalgam waste.

**R 338.11813 Amalgam separator; requirements.**

Rule 1813. (1) An amalgam separator that is installed in a dental office under R 338.11811 shall meet all of the following requirements:

- (a) Be certified as passing the international organization for standardization (iso) 11143:2008 standard for evaluating amalgam separators.
  - (b) Have a removal efficiency of not less than 95% as determined by the testing required under subdivision (a) of this subrule, based on the overall average of the 3 empty and the 3 simulated full test results.
  - (c) Be tested and certified by any of the following:
    - (i) SP technical research institute of Sweden.
    - (ii) Tuv nord, Germany.
    - (iii) NSF international.
    - (iv) Both of the following:
      - (A) A testing laboratory accredited by an accreditation body that is a signatory to the international laboratory accreditation cooperation's mutual recognition arrangement and has a scope of accreditation that includes iso 11143.
      - (B) A certification body accredited by an accreditation body that is a signatory to the international accreditation forum's multilateral recognition arrangement and has a scope of accreditation that includes iso 11143.
- (2) Any amalgam separator that meets the requirements of subrule (1) of this rule shall qualify as an amalgam separator approved by the board.

**R 338.11815 Collection, disposal, and recycling of dental amalgam waste; requirements.**

Rule 1815. (1) A dentist shall comply with all of the following:

- (a) Use amalgam only in a precapsulated form.
- (b) Salvage, store, and recycle non-contact and contact dental amalgam materials, including empty amalgam capsules. As used in this rule and R 338.11817, “recycle” or “recycling” means sending mercury or dental amalgam waste to either the contracted separator company or a facility in the United States that will reclaim or distill the mercury for reuse. “Recycle” or “recycling” shall not include any of the following:
  - (i) The on-site processing of mercury or dental amalgam waste.
  - (ii) The sale, donation, or exchange of mercury or dental amalgam waste through internet lists.
  - (iii) The sale or donation of mercury or dental amalgam waste to any individual or company for any other reuse purpose.
- (c) Collect and recycle extracted teeth or portions of teeth that contain dental amalgam materials.
- (d) Store all dental amalgam waste in enclosed and structurally sound containers until a sufficient amount has been collected for shipment to a reclamation facility or recycler or at a minimum, recycled annually.
- (e) Label all containers holding dental amalgam waste. The label shall include, at a minimum, the title “dental amalgam waste for recycling” and the date the waste was initially placed in the container.
- (f) Use chair-side traps to retain amalgam and recycle the content.
- (g) Recycle all amalgam materials collected in amalgam separators, vacuum pump filters, chair-side traps or other waste water processing devices.
- (h) Ensure that the separators operate properly and do not become full and bypass. This may include inspecting the separators annually, halfway through the operating life, or as required by the manufacturer.
- (i) Follow the steps for the cleanup of mercury spills as recommended by the department at [www.michigan.gov/mercury](http://www.michigan.gov/mercury).

(2) A dentist shall not do any of the following:

- (a) Store bulk elemental mercury that is not in capsule form.
- (b) Put dental amalgam waste down a toilet or drain.
- (c) Put dental amalgam waste or empty amalgam capsules into trash containers, or biohazard or infectious waste bags.
- (d) Disinfect teeth or any item containing dental amalgam by autoclaving or using heat.
- (e) Use cleaners containing bleach or chlorine to flush drains or wastewater lines.

(3) A dentist shall train and have written procedures for training dental office staff who manage or dispose of dental amalgam waste to ensure compliance with this rule.

(4) This rule shall not apply to a dentist listed in R 338.11811(2)(a) to (f). A dentist who installs and uses a holding tank and does not discharge amalgam waste shall comply with the requirements of subrule (1), (2), and (3) of this rule, as applicable.

### **R 338.11817 Record keeping.**

Rule 1817. (1) A dentist who is subject to the provisions of R 338.11811 shall maintain records at his or her dental office that include all of the following:

- (a) Type of amalgam separator installed, including the manufacturer and model.
- (b) Date the amalgam separator became operational.

- (c) Documentation verifying that the amalgam separator meets the requirements of R 338.11813.
  - (d) Documentation of the manufacturer's instructions for the operation and maintenance of the amalgam separator.
  - (e) Service records for each amalgam separator in use at the dental office that includes all of the following:
    - (i) Dates of maintenance.
    - (ii) Dates separator contents were recycled.
    - (iii) Name of the staff or contractor performing the service.
  - (f) Documentation verifying that the dentist disposed of and recycled any dental amalgam waste that was generated from the individual's dental office consistent with the requirements of R 338.11815. The documentation shall include all of the following:
    - (i) Name and address of the collection service or recycler.
    - (ii) Amount by weight of dental amalgam waste that was collected and the date it was collected or shipped from the dental office for recycling.
    - (iii) Name and address of the facility where the dental amalgam waste will be recycled.
    - (iv) Shipping or manifest papers documenting transfer of the dental amalgam waste to the recycler.
- (2) The records required under subrule (1) of this rule shall be provided upon request to an authorized state official, local public health department staff, or local municipality's representative.
- (3) All records required under subrule (1) of this rule shall be retained for a minimum of 3 years.

**R 338.11819 Verification.**

Rule 1819. A dentist who is subject to the provisions of R 338.11811 shall verify that he or she is in compliance with these rules and provide with each license renewal application the amalgam separator make and year that each separator was installed.

**R 338.11821 Compliance and enforcement.**

Rule 1821. Failure to comply with the requirements of these rules is a violation of section 16221(h) of the code and may result in sanctions as provided for in the code, or as otherwise provided for under state or federal law.