



ADVOCACY

## AGD Successfully Advocates for Changes to EPA’s Proposed Amalgam Rule

AGD was successful in advocating for changes to the Environmental Protection Agency’s (EPA) 2014 proposed rule on amalgam separators. In the final rule, issued June 14, 2017, by the U.S. Government Publishing Office in *Federal Register*, the agency accepted and incorporated all suggested changes as drafted in a Feb. 21, 2015, letter from AGD to the EPA.

AGD and its members have a strong commitment to patient safety. There was no disagreement as to whether amalgam separators would reduce the discharge of mercury to the municipal waterways. The areas of disagreement in the proposed rule were twofold: 1) the removal of at least 99 percent of amalgam, and 2) the declaration of dentists as dental industrial users (DIU). These two requirements penalized dentists who already use amalgam separators, including those already using International Organization for Standardization (ISO)-compliant amalgam separators.

### Changes to the Requirement of Amalgam Removal Efficiency

The proposed rule stated that amalgam separators must have “a removal efficiency of at least 99%” in addition to being compliant with ISO Standard 11143 requirements. The requirement that exceeded the ISO standard penalized dental offices that already use ISO-compliant separators by imposing

upon them the responsibility to monitor and measure their removal efficiency and to meet a removal efficiency at least 4 percent higher than the ISO standard.

AGD supports compliance with the American Dental Association’s (ADA) best management practices, which include the use of amalgam separators that comply with ISO Standard 11143 (requiring an amalgam removal efficiency of 95 percent, not 99 percent).

In the final rule, the EPA changed the requirement of amalgam removal efficiency to comport with the ISO standard of 95 percent removal. The EPA stated that its proposed requirement would have mandated that dental offices measure the percent removal achieved by the amalgam separator. This was not the intent of the agency. As a result, the EPA deleted the 99 percent removal requirement and changed it to the ISO standard.

### Changes to Regulatory Requirements

The proposed rule stated that dentists must declare themselves as DIUs. This designation would have created a new category to the Code of Federal Regulations section relating to pretreatment for existing and new sources of pollution. Dentists would have been required to submit to various inspections and reports, including a baseline

report, a 90-day compliance report and periodic monitoring reports.

These requirements would have created cost and time burdens on dentists that currently use amalgam separators. The EPA final rule negated this language and replaced the requirement with a one-time compliance report.

### Exemptions in the Final Rule

The EPA final rule exempts dental offices that do not place amalgam and remove it in only limited circumstances (less than 5 percent of procedures) from being required to have an ISO-compliant amalgam separator. Furthermore, the final rule does not apply to wastewater discharges from dental offices where the practice of dentistry consists exclusively of one or more of the following dental specialties: oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics or prosthodontics.

However, the EPA may not realize that in November 2016 through ADA House of Delegates (HOD) Resolution 65, ADA revised the *ADA Principles of Ethics and Code of Professional Conduct* to declare it ethical for specialists to practice all aspects of general dentistry, even if they advertise as specialists. As such, these specialists could include amalgam restorations as a part of their practices where their states allow them to do so and not be subject to the EPA’s amalgam separator final rule.

### Concessions in the Final Rule

Notwithstanding the specialists’ provisions, which were not apparent in 2014, AGD won major concessions from the EPA in the final rule. The cost and burdens imposed by the proposed rule requirements were not justified by any patient safety data. The new streamlined regulatory approach should reduce the onus on general dentists, while benefiting the environment.

To comment on or ask questions about the EPA final rule, email [practice@agd.org](mailto:practice@agd.org).

