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February 19, 2015

Electronic Delivery

Water Docket
Attention
Docket ID No. EPA-HQ-OW-2014-0693
Environmental Protection Agency
Mailcode: 4203M
1200 Pennsylvania Ave., NW.
Washington, DC 20460

Re: American Dental Association's (ADA) Comments on Dental Amalgam Separator Pretreatment Proposed Rule

Dear Sir or Madam:

The American Dental Association ("ADA") greatly appreciates the opportunity to review and comment on EPA's proposed Effluent Limitations Guidelines and Standards for the Dental Category, 79 Fed. Reg. 63,258 (October 22, 2014) (proposed rule) (Proposed Dental Amalgam Separator Standard).

The ADA is the largest dental professional association, representing over 158,000 dentists in the United States ("U.S."), including 64.5% of the active dentists. The vast majority of dentists utilize the services of their local sewage treatment plants (also called publicly owned treatment works or POTWs). The issuance of a pretreatment rule governing the discharge from dental offices would directly and significantly impact dentists and their patients. Additionally, dentists are concerned about the impact of environmental pollutants on their communities.

The ADA has promoted best management practices for dental offices (BMPs) since 2002. In 2009 the ADA amended its BMPs to include the use of amalgam separators that comply with the ISO Standard 11143. ADA partnered with the Environmental Protection Agency ("EPA") to encourage the voluntary installation of amalgam separators. In 2010, the ADA House of Delegates (the elected governing body of the ADA)¹ passed by unanimous consent a resolution supporting the promulgation of a Clean Water Act pretreatment rule

¹The ADA is a member-run organization managed by an elected Board of Trustees and a 473-member House of Delegates.

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governing applicable dental offices. ADA's support is contingent only on the final rule complying with nine common-sense principles, including use of amalgam separators that comply with the ISO Standard 11143. The ADA re-affirms its support of a pretreatment rule that requires amalgam separators consistent with these nine principles.

EPA's Proposed Amalgam Separator Standard demonstrates an effort to craft a proposal consistent with ADA's nine principles, but unfortunately includes several elements at odds with those principles. Indeed, in part, the EPA proposal is internally inconsistent. The ADA hopes that its comments will be viewed by EPA as constructive suggestions to improve its proposal, so that ADA can support it. **As currently written, ADA cannot support EPA's proposal.**

First, the implementation of the rule imposes undue and unnecessary burdens on dentists and the municipalities that operate POTWs). The ADA and the National Association of Clean Water Agencies (NACWA) have repeatedly pointed out in prior comments to EPA and the Office of Management and Budget that the amalgam pre-treatment rule should not impose an undue burden. The ADA believes such burdens result in little or no incremental benefit. In the ADA's view, some of the implementation requirements create undue and unnecessary burdens (e.g., requirements for excessive inspections and reports, which burden both dentists and POTW staff). The ADA defers to NACWA and the POTWs themselves with respect to burdens placed on the POTWs and share those concerns because some of those burdens will be transferred to the dental offices.

The ADA supports the exemption for oral pathology, oral and maxillofacial radiology, oral and maxillofacial surgery, orthodontics, periodontics, or prosthodontics. However, the final rule should also specifically use a de minimis exemption in lieu of "install or remove amalgam except in limited emergency circumstances." Specifically, the ADA proposes that De Minimis Dental Dischargers need not install a separator if the Dental Discharger removes on average 8 or fewer filings per month with the average calculated over the calendar year. That is, the number of removals each month during the calendar year are added together and divided by 12 and if the average is greater than 8, the de minimis exemption does not apply. The detailed comments illustrate the reasons that this exemption is de minimis, objective, and provable, if necessary. The ADA anticipates that this exemption will be used by specialty practices that are not otherwise exempted (i.e., not included in the specialty practices listed in § 441.10(b)), who perform placements or (who perform) removals for other dentists (e.g., while another dentist is away on vacation) or other "emergency" situations. The number of dentists who qualify for this exemption, therefore, will likely be very low.

Additionally, the de minimis exemption should include any dental offices where the effective date of the separator mandate is within one year of the date that the dental office

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will close (e.g., a dentist retires and closes his (or her) office). It would be a waste of resources to require a dentist to install a separator for six months, if the office will no longer be a source.

Second, the proposed rule is inconsistent with several aspects of the ISO Standard 11143. For example, the Proposed Rule requires installation of amalgam separators that comply with ISO Standard 11143. However, the Proposal also requires separators to meet a 99% removal efficiency requirement, rendering the reference to the ISO standard either meaningless or confused since the ISO standard requires an amalgam removal efficiency of only 95%.

Additionally, one of the reasons that the ISO standard uses a 95% amalgam removal efficiency (instead of a 99% amalgam removal efficiency) is that the sampling method used to measure the amount of amalgam captured is only validated through round robin testing at a removal efficiency of 95%. That is, the measurement method is only reproducible and accurate when measuring a removal efficiency of 95% or less. A 99% removal efficiency requires the accurate and reproducible measurement of very small quantities of amalgam and there is no standardized test method data that demonstrate the method can accurately and reproducibly measure a 99% amalgam removal efficiency. Furthermore, the use of 99% removal efficiency has been rejected by the ISO and ANSI.

The proposed rule also confuses a numerical test standard with a voluntary standard certification process by requiring “installation and operation of at least one 2008 ISO 11143 certified amalgam separator that ... [i]s certified to meet a removal efficiency of no less than 99.0%” Neither ISO nor the American National Standard Institute (ANSI) certifies compliance of amalgam separators with the ISO 11143 standard. The National Sanitation Foundation (NSF) evaluates amalgam separation against the requirements of ISO 11143 and certifies that the tested separator meets the ISO requirements. To our knowledge, no other laboratory in the US certifies compliance with ISO 11143.

However, formal certification is not necessary; only testing that the requirements are met should be required. EPA’s inappropriate use of “certified” language with respect to ISO compliance creates enforcement ambiguity in the rule, at best, and renders the rule contradictory at worst. Many manufacturers utilize other testing laboratories than NSF, even when EPA requires the testing be governed by a NSF standard.²

²For example, EPA’s definition of lead-free drinking water plumbing fixtures requires compliance with NSF Standard 61, Section 9 (<http://water.epa.gov/scitech/drinkingwater/dws/plumbing.cfm>). Yet compliance with this requirement can be demonstrated by testing from any laboratory that utilizes the NSF test method.

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Finally, the ISO standard relates to a capture efficiency for amalgam particles and not, as cited in the EPA's proposed rule, total mercury concentration. This is especially important because EPA in the notice of proposed rulemaking expressly rejected technology designed to capture dissolved mercury.

Accordingly, the proposed rule internally inconsistent, it calls for a removal efficiency not included in the ISO standard (which ISO concluded was not warranted) and it calls for separators meeting the ISO standard but which remove a certain percentage of "total mercury" even though the ISO standard provides a method for measuring particulate removal.

Third, EPA's choice of a new 99% removal efficiency requirement is particularly troubling to the ADA because it is inconsistent with prior EPA statements. EPA has repeatedly indicated that it would propose a rule that conformed to the ISO Standard 11143 (as stated in the ADA nine principles). The use of a 99% amalgam removal efficiency is inconsistent with EPA's prior positions (as the ADA understood them) since the ISO standard requires a 95% removal efficiency (based on the extensive ISO method development and measurement quality assurance and quality control process).

Fourth, the incremental amalgam (and therefore mercury) captured by a separator with a purported amalgam removal efficiency of 99% is de minimis compared to the amount of amalgam removed by a separator with a 95% removal efficiency (*see* calculations in the ADA's detailed comments). In fact, according to EPA, the average removal efficiency of the existing separators that meet the ISO standard is 99% or more so there is no incremental benefit on average using the existing ISO standard removal efficiency requirement. In states with existing 99% removal efficiency requirements³, there would be no increase in benefit. By definition, setting a removal efficiency that cannot be below 95% results in a mean removal efficiency that is significantly higher than 95%. Moreover, as noted already, the ISO standard test method does not provide a validated method of measuring that level of efficiency.

Fifth, EPA's calculated cost-effectiveness for the Proposed Dental Amalgam Separator Standard is flawed and grossly overstates the proposal's cost-effectiveness. EPA's cost effectiveness calculation is flawed and, in fact, ignores the primary benefit of the proposed rule, from ADA's perspective: enhanced levels of waste amalgam made available for recycling. Indeed, this benefit is the primary reason ADA supports the use of amalgam separators.

³Some states do require 99% removal efficiency. This creates some of the same ambiguities noted here by ADA. To ADA's knowledge, these issues have never been addressed with respect to the state statutes.

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The ADA believes that the regulatory record must be accurate with respect to cost effectiveness so that incorrect data and assumptions do not take on a life of their own and end up being misused in other contexts. Accordingly, the ADA offers the following observations with respect to EPA's calculations.

EPA underestimates the cost of installing and operating amalgam separators, overestimates the amount of mercury and other metals captured by the combination of chairside traps, vacuum filters, amalgam separators, and the POTW,⁴ and fails to justify the use of a weighting factor for mercury and the other metals.

If just the errors in the calculation of the cumulative amount of amalgam removed are corrected, the cost per equivalent toxic pound of all of the metals in amalgam⁵ for compliance with the Proposed Dental Amalgam Standard exceeds the EPA cost criteria utilized to determine if a pretreatment rule is cost-effective.

The most significant refinement in the EPA's calculations is the need to accurately calculate the cumulative amount of amalgam removed prior to discharge into the surface water all of the amalgam removal devices specified by the Proposed Dental Amalgam Separator Standard. EPA assumes that after the chairside trap and the vacuum filter remove 78% of the amalgam, the amalgam separator removes 99% of remaining 22%, and the POTW removes 90% of the 0.22% leaving the dental office. However, amalgam particles have a distribution of sizes and each component in the amalgam removal scheme removes only particles above a given size. The maximum amalgam removal efficiency for a separator, the chairside traps, the vacuum filters, and the amalgam separator is 99%⁶ (i.e., the 1% of the amalgam not captured by the amalgam separator is not captured by the chairside trap and vacuum filter). In other words, these capture devices are in some ways redundant (albeit with different efficiencies

⁴EPA both underestimates the amalgam removal efficiency of POTWs and overestimates the cumulative amalgam capture efficiency of the combination of the chairside trap, vacuum filter, separator, and POTW. For example, since the median existing removal efficiency for separator currently on the market is 99% (according to EPA), requiring a removal efficiency of 99% will eliminate roughly half of the amalgam separator models now available and is likely to increase the costs (based on the law of supply and demand). This increase should be considered by EPA. The overestimation is summarized in the next paragraph in the text, below.

⁵EPA adjusts the pounds of mercury, pounds of silver, pounds of tin, etc. in the amalgam captured if the Proposed Dental Amalgam Separator Standard is implemented. In effect, EPA increases the pounds of each metal in amalgam that is captured based on that metals relative toxicity to other metals. This calculation is explained in the Detailed Comments.

⁶For purposes of this part of the ADA's comments, we are using EPA's 99% figure. Please see our detailed comments for a discussion of the ADA's position and the relationship to the ISO standard incorporated by EPA.

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for different sized particles). Similarly, the 1% of the amalgam discharged into the POTW from the dental office consists of particles too small to be collected by POTWs (unless the POTW amalgam removal efficiency is greater than 99%). Thus, the cumulative removal efficiency (if the proposed rule is implemented) is equal to the most efficient capture device in the chain (*i.e.*, 99% if an amalgam separator is utilized). EPA's calculated removal efficiency is simply physically impossible.

This calculation is more important in assessing the cost-effectiveness of removing dissolved mercury derived from dental amalgam, *i.e.*, the calculated cost per pound of toxic equivalent for removing discharged metals from amalgam is far higher than EPA's own regulation screening value because very little incremental amalgam is removed by treating the dissolved mercury.

Sixth, EPA fails to estimate even roughly the reduction in methylmercury levels in fish due to the implementation of the Proposed Dental Amalgam Standard (*i.e.*, the benefit of the proposal) even though EPA and other federal agencies have historically done so in other regulatory proceedings and peer reviewed in studies. In fact, such historic evaluations of the contribution of mercury concentrations in fish from electric utility emissions consistently demonstrate that discharges of dental amalgam related mercury into rivers and other waterbodies has little contribution to the methylmercury levels in fish from all sources.

The ADA believes that each of the flaws it identified in the Proposed Dental Amalgam Standard and the administrative record supporting the proposed rule can be modified to create a rule that is internally consistent and protective of the environment while not unduly burdensome. The ADA requests (and principles of administrative law require) EPA to justify clearly and explicitly the rationale for its departures from the ISO standard. EPA must document the cost impacts, the cost-effectiveness of using 99% versus 95%, and the incremental benefits, if any, of using 99% versus 95% removal efficiency.

In addition, accompanying this cover letter are the ADA's detailed comments (which support the summary provided above and provide other more specific comments). As a continued evidence of the ADA's good faith and its commitment to a reasonable and effective Amalgam Separator Standard, Attachment 1 to the detailed comments provides a red line copy of regulatory text, as well as a copy of the regulatory text without redlining as the ADA proposes to amend it. Attachment 2 to the detailed comments provides the Certification of Fredrick Eichmiller, which describes the ISO and ANSI voluntary standards process and the ISO dental amalgam separator standard.

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As always, the ADA looks forward to working with EPA to resolve these disagreements. If you any questions, please feel free to call or e-mail me or the ADA representatives.

Respectfully,

A handwritten signature in black ink that reads "William J. Walsh". The signature is written in a cursive style with a large, prominent "W" at the beginning.

William J. Walsh
Pepper Hamilton LLP
On behalf of the American Dental Association

Attachments

cc: Jerome Bowman, ADA
Jeff Troupe, ADA