

Dental Amalgam: Regulating Its Use and Disposal

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ABSTRACT

Although dental amalgam has been a restorative material for more than 150 years, government regulation of its use and disposal came much later with the creation of new federal laws and agencies. None of the federal laws regulating dental amalgam today were written specifically to regulate amalgam. Instead, these new laws and agencies were created to address broad public safety concerns, where little or no regulation existed before, in the areas of medical devices and drugs and environmental pollution. It is the interpretation and implementation of environmental laws that recently have had the greatest impact on dental practices.

Dental amalgam and its components are medical devices regulated by the U.S. Food and Drug Administration (FDA) under the authority of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Dental amalgam was already in use at the time of the 1976 amendments, so it and other existing medical devices were assigned to one of three “classes.” Class I devices pose the lowest risk and are subject to the least level of controls. Class II devices are subject to additional special controls because they are devices that pose incrementally greater risk and their safety and effectiveness cannot be adequately controlled by Class I controls. Class III devices are the riskiest devices and have the most controls placed upon them.

Dental mercury is regulated as a Class I device. Dental amalgam alloy (silver, tin, copper and sometimes, other metals) is regulated as a Class II product because of “potential risks that could result from variations in chemical formulation related to percent composition and types of materials.”¹ Amalgam in capsules (alloy and mercury that are separately sealed and sold in single-use capsules) has never been classified, but is regulated as a Class II device because one of its components is regulated as such.

In February 2002, the FDA proposed a rule to bring all amalgam products

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into Class II. The FDA wants to require ingredient labeling and conformance to international standards.² Two public comment periods were provided for the proposed rule. The FDA has analyzed the comments, but the rulemaking has been placed on hold until after a forthcoming scientific literature review related to the health effects of dental amalgam in humans is completed.³ In conjunction with the U.S. Public Health Service and the National Institute of Dental and Craniofacial Research, the FDA has contracted with an independent firm to conduct the literature review, which is expected to be completed in 2004.⁴

Environmental

Wastewater

Dental office wastewater regulations are enforced primarily by state and local agencies in accordance with authority delegated to them under the federal Clean Water Act (CWA). If the EPA finds that a state or local authority has not carried out its responsibilities under the CWA, then the EPA can promulgate or enforce the necessary regulations. The EPA also has the authority to review state water quality programs to ensure compliance with the CWA. States and their subdivisions can also regulate wastewater under independent state and local laws. However, state regulations must be at least as stringent as federal regulations, and can be more stringent.

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relies on the concept that “preventive” regulation is the best method to address environmental concerns. This law was enacted during a time when public concern about environmental pollution was very high, and there was strong political consensus for broad environmental legislation. The CWA allows the EPA to set wastewater discharge limits for industries, to set water quality standards for lakes, rivers, and bays, and to manage federal funding for construction of sewage treatment plants. Amendments to the law and recent implementation strategies have led to an evolution from a source-by-source, pollutant-by-pollutant approach to one that is more holistic, considering the physical and biological integrity of the surface waters and not just chemical characteristics.⁵

The EPA uses a series of assumptions or policy judgments that collectively can be referred to as “precautionary principles.” These policy judgments may have strong theoretical rationale, but may or may not be supported strongly by scientific data. The EPA’s regulatory approach is based on these policy judgments, and recognizes that there are financial and technical limitations, on acquiring the scientific data necessary to ensure the policy judgment is valid. Many industries have mounted well-financed legal challenges to the EPA’s regulatory approach, but the courts have held that the agency is not required to support its findings with a high degree of scientific certainty.

With regard to dental amalgam and

mercury, the EPA assumes all forms of mercury have the potential to convert to the more toxic and bioavailable methylmercury. This has not been scientifically proven, but it is the basis for the EPA’s actions to eliminate or reduce the use of mercury, and to set limits on mercury discharges to the environment. The EPA then sets the standard that state and regional water boards must enforce against local sanitation agencies and other dischargers.

According to the ADA, “EPA’s aggressive pollution prevention initiative and CWA implementation measures are the driving forces for the increased regulatory scrutiny ... Neither EPA nor Congress is likely to change a fundamental pillar of its regulatory scheme even if the impact of the regulatory framework is unduly harsh and inefficient in achieving the statutory goals when applied to dentists. There is no simple, cost-effective research project that is likely to convince EPA to exempt dental offices from this regulatory scheme ... Literally hundreds of millions of dollars have been or are being expended by EPA, the states, and industry on many of these issues. Therefore, ADA is unlikely to prevail by simply presenting a new study.”⁶

State and regional water quality boards must establish policy and regulations consistent with federal law. The EPA has established a limit of 0.05 mg/l or ppb for surface waters in most states, but as noted, states and local agencies can set more stringent limits. Examples of current discharge limitations are:

- EPA 0.05 mg/l or ppb
- California Toxics Rule 0.025 mg/l or ppb
- Great Lakes 0.0013 mg/l or ppb
- Maine (proposed) 0.0002 mg/l or ppb

It is widely believed that the California Toxics Rule limit will be lowered in the near future.

To provide a sense of how low these numbers are, one part per million is roughly equivalent to a pinch of salt in one ton of potato chips. One part per billion is roughly equivalent to a pinch of salt in one thousand tons of potato chips.

The EPA encourages pollution prevention and source reduction. Source reduction typically involves efforts to eliminate the use of mercury-containing products. Sanitation agencies view pollution prevention and source control as the most cost-effective methods to meet their treatment plant permit limits. Dentists have asked if treatment plants have considered implementing other systems or processes to improve their plants' ability to capture mercury. Plant operators have responded that options have been explored, and that reverse osmosis systems could be effective. However, those systems cost in the millions of dollars, generate their own hazardous waste streams that must be managed and require the use of more land than treatment plants generally have available.

In the past year, the cities of Los Angeles, San Francisco, and Palo Alto have formalized regulatory programs for dental office wastewater. Other communities, especially in the San Francisco Bay Area, are considering the implementation of regulatory programs. For other communities that do not face further restrictions on mercury, an educational campaign on best management practices for dental waste is a likely alternative to regulation.

Regulated Waste

California's hazardous waste laws and regulations, unlike their federal equivalents, apply to dental amalgam. Prior to the adoption of "universal waste" regulations effective March 2003, amalgam waste that could be classified as scrap metal could be recycled and exempted from hazardous waste regulation. Other amalgam wastes that contained very fine particles, such as sludge from the vacuum filter and chairside

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traps, were regulated as hazardous waste. Hazardous waste regulation limited options for waste disposal and increased regulatory paperwork and oversight.

Under the universal waste regulations, all amalgam waste can be managed as universal waste, that is, it should be recycled. If the amalgam waste is not recycled, it is considered hazardous waste subject to hazardous waste regulatory requirements. The California Department of Toxic Substances Control determined that amalgam waste meets the criteria to be designated universal waste. These criteria include: (1) the waste is generated by a large number of businesses frequently and in relatively small quantities by each generator; (2) there are systems in place to ensure close stewardship of the waste; (3) the risk posed by the waste is relatively low compared to

other hazardous wastes, and (4) regulation as universal waste will promote safe and effective collection and recycling.⁷

The universal waste regulations require adherence to specific amalgam waste management practices. They are:

- Do not rinse amalgam-containing traps, filters, or containers in the sink.
- Do not place amalgam, or amalgam-containing traps and filters with medical waste or regular solid waste.
- Recycle or manage as hazardous waste non-contact and contact amalgam (including extracted teeth with amalgam).
- Recycle or manage as hazardous waste amalgam-containing waste from traps and filters.
- Keep amalgam waste in an airtight container.

Dental offices should be aware that other mercury-containing products may also be managed as universal waste, such as thermometers, lamps, batteries, and switches in some appliances. **CDA**

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2. Dental Amalgam, Request for Information, Federal Register 68(90); 25047-8.

3. Personal communication with Susan Runner, DDS, FDA Center for Devices and Radiological Health, May 30, 2003.

4. Life Sciences Research Office Dental Amalgam page, http://www.lsro.org/amalgam/frames_amalgam_general.html, April 12, 2004

5. "Introduction to the Clean Water Act," Environmental Protection Agency, <http://www.epa.gov/watertrain/cwa/>, April 12, 2004

6. "Assessment of Potential Components for an American Dental Association Action Plan to Address the Discharge of Dental Amalgam Into Sewerage Treatment Plants," American Dental Association, 2001.

7. Mercury Waste Classification and Management, Final Statement of Reasons, California Department of Toxic Substances Control, http://www.dtsc.ca.gov/LawsRegulationsPolicies/Mercury/Oeara_regs_merctfsor.pdf, April 12, 2004.

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