## CLINICAL

# New dental amalgam handling regulations what every dentist needs to know

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# Regulations regarding the handling, use, storage and disposal of dental amalgam (and its wastes) are now law in South Africa.<sup>1</sup>

Before we look at the detailed requirements placed on all dentists nationwide, let's take a few moments to review how we arrived at this point in history. Dentists (in my experience) are often reluctant to change behaviors when they do not perceive there to be a problem. Hopefully, this brief background will help to elucidate why we must change our behaviors and comply with these regulations.

Dental amalgam has been used as a restorative material for over 150 years. It is a metallic alloy composed of mercury, silver, copper and tin with mercury comprising about 50% of the material.

In recent years it has been found that current practices regarding amalgam waste handling and disposal result in sizable quantities of mercury being released into the environment from dental facilities, contributing to a build-up in the global environment. Mercury-containing amalgam wastes (both solid and liquid) enter the environment when new restorations are placed and when old amalgams are removed and the waste produced is flushed into chair-side drains. Globally, an estimated 340 tons of mercury is used per year in dentistry. Of this amount, approximately 70 to 100 tons enters the solid waste stream.<sup>2</sup>

The anthropogenic release of mercury in dental wastewater is of great concern because it poses a serious risk to human health. Once mercury is released into the environment through discharge into sewers (for example), it eventually finds its way into rivers, lakes and oceans. Here, sulfate reducing bacteria transform it into methylmercury (MeHg), a persistent, bio-available and bio-accumulative neurotoxin that, even in minute quantities, poses risks to human health, wildlife and the environment as a whole.

This transformation of elemental mercury into methylmercury (its organic form) occurs when amalgam bonds are broken. A simple analogy to demonstrate this is as follows: Sodium (Na) and chlorine (Cl) are both highly toxic in their elemental states. Once combined to make salt (NaCl) the individual elements are no longer hazardous as they are in a bound state. In much the same way, mercury is toxic in its elemental form. Once combined into an amalgamated state, it loses its toxicity due to the bonds it forms with the other elements in the alloy. This remains the case until such time as the bonds of the amalgam are broken. This bond cleavage can happen by exposure of the amalgam to conditions of high heat or high alkalinity. Once broken, the elemental mercury liberated may be changed by bacteria into its organic form.

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Once in lakes or other bodies of water, the mercury is taken up by aquatic plants. These are consumed by small fish that, in turn, are consumed by larger fish which become part of the human diet. This process of bio-accumulation means that the mercury becomes concentrated, and levels increase, as it moves up through the food chain.<sup>3-5</sup>

If solid amalgam waste is disposed of with regular trash or bio-hazardous/infectious waste, it will almost always be incinerated. The heat from this process ruptures the amalgam bonds and mercury is released. This mercury, then, can become atmospheric and travel great distances to deposit on the surfaces of lakes and other bodies of water we just discussed. If this waste is land-filled and not incinerated, the high heat generated by material degradation deep within the landfill can also cause a disruption of the amalgam bonds. Mercury gases can then be released into the atmosphere or liquid mercury may seep downward contaminating ground water supplies.

With dentistry, amalgam can also leave the office when untreated wastewater exits the dental facility. This water can contain high amounts of fine particulate amalgam from the process of removing old restorations. As a general rule, approximately 30% of dental amalgam waste is in this form and approximately 70% is in the form of solid waste.

Mercury has a wide range of impacts on human health, especially on developing fetuses and young children. Neurological and behavioral disorders can be a result of mercury toxicity. Symptoms associated with toxicity include tremors, insomnia, memory loss, neuromuscular effects, headaches, cognitive and motor dysfunctions. Links to cardiovascular disease have been noted in recent studies as well, with observed impacts on cardiovascular end points like acute myocardial infarctions, hypertension and changes in heart rate variability.<sup>5,6</sup> In the most vulnerable of populations, young children, toxicity can cause irreversible neurological damage resulting in seizures, mental retardation, vision and hearing loss, delayed development, language disorders and memory loss.

The most severe episode of mercury poisoning to date happened in the Japanese fishing village of Minamata in 1956. From 1932 until 1968, the Chisso Corporation, a chemical manufacturer, released industrial wastewater contaminated with high levels of methylmercury into Minamata Bay.

Diseases related to mercury poisoning were found, often with several cases per family, to be clustered along the shores of Minamata Bay primarily in small fishing villages where consumption of fish and shellfish was high. The first case of the disease was seen in 1956 in a five-year-old girl who presented with symptoms that included dysbasia (difficulty walking), dysarthria (difficulty speaking) and convulsions. Later, her younger sister and neighboring children were admitted to the hospital with similar symptoms.<sup>7</sup> Not until two years after these initial presentations was the cause for the bizarre neurological symptoms found to be poisoning with extremely high levels of methylmercury.

In 2013, the United Nations International Negotiating Committee was formed. It was tasked with developing measures among nations regarding the control of the supply of, and trade in, mercury and mercury containing materials and devices including amalgam. This culminated in what is known as the Minamata Treaty. South Africa, being a signatory to the treaty, agreed to develop regulations to control mercury within the country. That action has manifested itself in the Regulations on Dental Amalgam which we have today.

It is interesting to note that the Minamata Treaty does not call for an outright ban on the use of amalgam. While a total phase-out of certain mercury containing products is called for, the treaty looks to participating countries not to ban, but rather to both phase-down the use of dental amalgam as a restorative material and also to ensure the proper capture and recycling of amalgam wastes.

While a phase-down in dental amalgam use is a tenet of the Minamata Treaty, an outright ban on its use is not. Amalgam remains a safe and effective restorative material, ideally suited for high stress bearing surfaces and for use in areas where a dry field is near impossible to achieve. Being less technique sensitive and far more economical than most alternative restorative materials currently available, it is an ideal material for use in both developing and under developed areas which may have higher than average caries incidence rates.<sup>8,9</sup>

Amalgam restorations are safe, beneficial and help to keep the cost of healthcare down. What is most important here, and I cannot stress this enough, is that all wastes of amalgam must be collected and properly recycled. The government now mandates you do this. As a clinician who cares for the health of patients, you should also do it because it is the right thing to do.

That waste management (handling, storage and recycling) is what we will turn our attention to now as we discuss the new rules in South Africa pertaining to mercury in general and amalgam in particular.

The government of South Africa ratified the Minamata Treaty in 2019. Since domesticating the treaty, the

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government has formulated rules for import, export, use, distribution, phase-out, phase-down, and all other aspects regarding mercury in general. Dental amalgam use, and dental amalgam waste management (storage, disposal and recycling) regulations are aimed at keeping this material out of both the solid waste stream as well as dental wastewater.

The language for the new requirements can be found in "The Regulations for the Management of Mercury in South Africa, section 25(3), with section 47(1), of The National Environmental Act, 1998 (Act No. 107 of 1998)". These regulations were published under Government Notices, No. 6073, 31 March 2025, Dept. of Forestry, Fisheries and the Environment, as Regulations for the Management of Mercury in South Africa.<sup>1</sup>

#### These regulations apply to all dental facilities where amalgam is either placed or removed or where teeth containing amalgam are removed.

While the regulations cover a host of topics and industries, the purposes of these regulations relevant to the practice of dentistry are:

- 1. To eliminate the anthropogenic releases of mercury into the environment
- 2. To manage the processes releasing mercury into the environment
- 3. To phase-down dental amalgam usage

# The specific requirements for dentists regarding amalgam usage and recycling are as follows:<sup>8,1</sup>

- 1. Phase-down, where possible, the use of amalgam.
- Use only pre-dosed, encapsulated amalgam. The mercury content of the capsules may not exceed 0.58 ml. Use or possession of bulk mercury in the office is not allowed.
- 3. Employ Best Management Practices when either placing or removing dental amalgam in order to reduce amalgam waste.
- 4. Use chair-side traps and vacuum pump filters to capture larger amalgam pieces.
- 5. Scrap amalgam (including empty plastic capsules from pre-capsulated alloy, excess mix or carvings, chair-side and vacuum pump traps and extracted teeth containing amalgam should all be placed in a special container and sent for amalgam recycling as this "scrap" accounts for about 70% of the amalgam/mercury waste a practice generates.
- 6. Amalgam separators (which capture the remaining 30% of fine particulate amalgam from the

wastewater stream) must be installed by March 31, 2025. By the reporting deadline of March 31, 2026, these separators must function at 95% efficiency. It is my recommendation that the most cost-effective option is simply to install a 95% efficient separator now.

- Amalgam separators must be maintained according to the manufacturer instructions to ensure the highest practical level of retention.
- Dental practitioners may not release amalgam waste, directly or indirectly, into the environment under any circumstances. (For this reason, it is imperative that the unit you use not be prone to back-ups as this can cause a by-pass situation which would be a violation).
- 9. Safely store all amalgam waste for collection and recycling.
- 10. Ensure that all amalgam waste is safely disposed of (sent for annual recycling in the case of our company).
- 11. Dental amalgam is not to be used in the treatment (restoration) of deciduous teeth, in patients under 15 years of age, in pregnant women or breastfeeding women (except when considered absolutely necessary by the dentist based on the needs of the patient).
- 12. Purchase your amalgam from suppliers within South Africa. I say this as you may still use amalgam and will have to file reports. If, however, you buy amalgam from outside the country, you would be considered an importer and subject to additional regulations and permitting that you could easily avoid by purchasing from an in-country supplier.

### **Regarding registration and reporting:**

Within 90 days of the commencement of these regulations (the regulations went into effect on March 31, 2025 – so within 90 days of that date), the dental office must register with the Minister by submitting the Registration form. This form can be easily found in the published Regulation and printed off.1 Dentists must register as they place and or remove amalgam (see Registration Form, B. "type of registration applied for" where dentists are listed as members of the grouping in Annexure A (3), sub-parts viii and ix).<sup>1</sup>

Further, the dental office must submit to the Director-General, by e-mail at <u>MercuryRegs@dffe.gov.za</u> or registered mail to the Department of Forestry, Fisheries and the Environment, 473 Steve Biko Street, Arcadia, Pretoria, an annual report (submitted not later than March 31 of each year) detailing the implementation of measures taken by the practice related to their phase-down of the use of dental amalgam.<sup>1</sup> Dental offices must develop a dental amalgam phasedown plan for their practices.1 The Dept. of Forestry, Fisheries and the Environment will allow the submission of the plan by a dental association on behalf of its members. This does not, however, absolve the individual members from the responsibility, liability and accountability for compliance with these Regulations. If you are a member of SADA, contact them and enquire if they will be filing on their members' behalf.

The following material would only apply to non-member dentists (assuming the dental society does file on behalf of its members) who would need to file the annual report.

What must be reported is progress made in terms of a dental amalgam phase-down plan. There are a number of measures (11 minimally) to be considered in the phasedown plan. Of these, only 5 are under the direct control of the dentist and are, therefore, relevant to the individual practitioner. The remaining 6 relate to dental associations, insurance companies and others outside of the dentist's direct purview and so I have not included them in the below list. The 5 you need to be concerned about in the individual or group practice setting are:

- Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restorations in your practice.
- Restricting the use of dental amalgam to the pre-dosed, encapsulated form containing not more the 0.58 ml of mercury.
- 3. Never having/using bulk mercury in the office.
- 4. Utilizing best environmental practices to reduce releases of mercury and mercury compounds to water and land. (This means recycling scrap amalgam and using amalgam separators as previously discussed). Remember, the dentist may not release amalgam, directly or indirectly, into the environment under any circumstances.
- 5. Do not use dental amalgam for the treatment (restoration) of deciduous teeth, in patients under 15 years of age, in pregnant women, or in breastfeeding women (except when considered absolutely necessary by the dentist based on the needs of the patient).

#### **Penalties**

Penalties for any dentist who violates the new regulations are harsh so be sure you are in full compliance. Penalties vary based on which part of the regulation has been violated.

First conviction for certain offences could yield a fine of R5 million or a maximum period of imprisonment of 5 years.

Second or subsequent convictions for these same offences could result in a fine increasing to a maximum of R 10 million or a maximum period of imprisonment of 10 years. Various other offences (deemed less severe) could, upon conviction, still result in a maximum fine of R500,000.

The bottom line is to maintain your practice in full compliance at all times and avoid problems.

#### To summarize:

- Never allow mercury/amalgam or its wastes to enter the environment.
- 2. Always:

• Use an amalgam separator. This must be used as of March 31, 2025 and must be at least 95% efficient as of March 31, 2026. (Better, in my opinion, to simply place the more efficient unit now and avoid the cost of replacing it in less than a year).

• **Recycle all scrap amalgam**. We previously described what constitutes scrap. This is placed in a specially designed container and sent out for recycling.

- 3. Always use pre-dosed encapsulated alloy.
- 4. File all required reports in a timely manner.

#### **References:**

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#### Disclosure:

Dr. Frost is Vice President for Clinical and Scientific Affairs for Dental Recycling International, Inc. (DRI) and for Dental Recycling North America, Inc. (DRNA). He is also Director of Continuing Dental Education.

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