

Code of Practice regarding:

Dental Amalgam

Promoting transparency and enhancing public
confidence in the dental profession

JULY 2018

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Introduction

The European Union has introduced regulation 2017/852 to implement the Minamata Convention on Mercury. This is an environmental regulation rather than a health regulation and its purpose is to reduce the amount of mercury used in many industries and professional sectors, including dentistry. This EU Regulation is binding in its entirety and directly applicable in all Member States.

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Overview of EU Regulations

The regulations, among other things, place restrictions on the import and export of mercury, the manufacture of mercury based products, mining, and the storage of mercury. Article 10 of the regulations sets out the parameters for the use of dental amalgam:

1. From 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form. The use of mercury in bulk form by dental practitioners shall be prohibited.
2. From 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.
3. By 1 July 2019, each Member State shall set out a national plan concerning the measures it intends to implement to phase down the use of dental amalgam. Member States shall make their national plans publicly available on the internet and shall transmit them to the Commission within one month of their adoption.
4. From 1 January 2019, operators of dental facilities in which dental amalgam is used or dental amalgam fillings or teeth containing such fillings are removed, shall ensure that their facilities are equipped with amalgam separators for the retention and collection of amalgam particles, including those contained in used water. Such operators shall ensure that:
 - a. amalgam separators put into service from 1 January 2018 provide a retention level of at least 95 % of amalgam particles;
 - b. from 1 January 2021, all amalgam separators in use provide the retention level specified in point (a).Amalgam separators shall be maintained in accordance with the manufacturer's instructions to ensure the highest practicable level of retention.
5. Capsules and amalgam separators complying with European standards, or with other national or international standards that provide an equivalent level of

quality and retention, shall be presumed to satisfy the requirements set out in paragraphs 1 and 4.

6. Dental practitioners shall ensure that their amalgam waste, including amalgam residues, particles and fillings, and teeth, or parts thereof, contaminated by dental amalgam, is handled and collected by an authorised waste management establishment or undertaking.

Dental practitioners shall not release directly or indirectly such amalgam waste into the environment under any circumstances.

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Ethical Obligations for Dentists

Dentists have an ethical as well as a legal obligation to comply with these regulations. To comply with the regulations dental practitioners must:

1. Ensure that valid and explicit consent has been obtained to treat a patient using dental amalgam if it is being used for the treatment of deciduous teeth, in children under the age of 15 or of pregnant or breastfeeding women. This consent must be obtained in compliance with the Dental Council's Code of Practice regarding Professional Behaviour and Ethical Conduct, as amended from time to time, and be noted in the patient's record. The records should show clearly that a decision to proceed with the use of amalgam was made with the full knowledge and understanding of the patient or parent.

(With effect from 1 July 2018)

2. In the cases above, record the specific clinical reasons why, in the dentist's opinion, it is necessary to use dental amalgam. The best interests of the patient are paramount when considering appropriate treatment. If the care of a patient's either oral or general health could be compromised or made worse through the use of either an alternative, or no restorative material, then there may be a justification for the use of dental amalgam to prevent harm to the patient. The dentist's opinion of the clinical justification for the use of amalgam should be clearly recorded in the clinical notes.

(With effect from 1 July 2018)

3. Only use dental amalgam in pre-dosed encapsulated form complying with European standards, or with other national or international standards.

(with effect from 1 January 2019)

4. Maintain proper records regarding the retention levels, the installation, commissioning and maintenance of dental separators installed after 1 January 2018. All separators must provide a retention level of at least 95%.

(with effect from 1 January 2019)

5. Dentists are prohibited from directly or indirectly releasing amalgam waste into the environment under any circumstances. Under the Waste Management Act, 1996 and regulations dentists must ensure that all amalgam waste is collected by a waste management undertaking authorised for that purpose and retain proper records of its disposal.

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Existing Obligations and Compliance

Dentists have an existing obligation under the Dental Council's Code of Practice regarding Infection Prevention and Control to install amalgam separators which retain at least 95% of amalgam particles. The requirements in this Code are in addition to these pre-existing obligations.

A failure to comply with these regulations and this Code of Practice may be deemed to be serious falling short in the standards expected of a dentist and may result in fitness to practise proceedings under the Dentists Act, 1985.

Dentists should note that failure to comply with the Waste Management Act, 1996 and regulations may result in separate proceedings by other authorities.