



Guidance Document for Federal Dental Regulation 40 CFR 441
Implemented by the City of Fort Collins Industrial Pretreatment Department

Determining Requirements for your Office

Under 40 CFR 441.10, dental facilities can be categorized in several different ways. Depending on the classification of your dental practice the federal regulation requires that at a minimum, an Initial Compliance Report be completed and a copy of it be maintained onsite for as long as the facility is in operation, or until ownership is transferred. Use the guidance below to help determine which category you fall in to (then complete Section 1 on the Initial Compliance Report Form). Each category listed below describes the what is required of your dental facility.

Use the descriptions below to help complete **Section 1** of the Initial Compliance Report Form for 40 CFR 441

This practice regularly performs one or more procedures per month involving the placement or removal of amalgam.

Your facility falls into this category if your office exclusively practices one of the following disciplines **and** performs procedures where mercury amalgams are either placed or removed on a regular basis.

Disciplines: General Dentistry, Pediatric Dentistry, Endodontics, or Other.

***If this describes your practice, then you must complete steps 1-7 below. Maintain copies (electronic or hard copies) of all required documents onsite.

1. Complete and submit the Initial Compliance Report.
2. Retain a copy the Initial Compliance Report for the duration of facility operation or until ownership is transferred. *If ownership changes, a new compliance form must be completed and retained.
3. Install an amalgam separator.
4. Implement and certify that Best Management Practices are being implemented.
5. Maintain operation and maintenance logs as described below.
6. Complete annual certifications with updated information.
7. Maintain copies of the above documentation onsite and make available during inspections of this facility.

This practice only performs procedures involving the removal of amalgam in emergency situations and does not store amalgam capsules. *For the purposes of this Program, emergency situations are quantified as <5% of total procedures.*

Your facility falls into this category if your office exclusively practices one of the following disciplines and only performs procedures where mercury amalgams are removed in limited emergency or unplanned, unanticipated circumstances. No amalgam must be onsite at your facility.

Disciplines: General Dentistry, Pediatric Dentistry, Endodontics, or Other.

***If this describes your practice then then complete and return the attached Initial Compliance Report. Maintain copies of the completed document onsite. Each office certifying that no amalgam is used may be individually verified with an onsite inspection of the facility by the Fort Collins Industrial Pretreatment Department.

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- This practice does not perform any procedures involving the placement or removal of amalgam. If you select this item, please check one of the following explanations.**
- This office specializes exclusively in Oral Pathology, Oral and/or Maxillofacial Radiology or Surgery, Orthodontics, Periodontics, or Prosthodontics.**
 - Other explanation:**

Your facility falls into this category if your office exclusively practices one of the following specialties or is a mobile dental unit.

Specialties: Oral Pathology, Oral and/or Maxillofacial Radiology, Oral and/or Maxillofacial Surgery, Orthodontics, Periodontics, or Prosthodontics.

***If this describes your practice then then complete and return the attached Initial Compliance Report. Maintain copies of the completed document onsite.

Dental Amalgam Control Program Requirements

Amalgam Separator(s)

The amalgam separator(s) used at your facility must meet the following requirements.

1. Amalgam separators shall meet or exceed current ISO 11143 (2008) standards.
2. The amalgam separators must be properly sized for your dental facility.
3. All wastewater that may contain amalgam waste must pass through an amalgam separator.
4. Amalgam separator collection containers must allow for inspections of sludge levels. These visual inspections must be logged and logs must be made available during inspections.
5. The amalgam separators must be maintained in accordance with manufacturer's recommendations.
6. Documentation for maintenance and recycling must be maintained and made available during inspections.
7. Collection containers and other amalgam waste must be disposed of or recycled in a manner that satisfies all federal, state and local regulations.
8. Amalgam separators must be replaced within the manufacturer's timelines.

Best Management Practices

Best Management Practices (BMPs) are enforceable Industrial Pretreatment standards.

The following items must be in place at your facility if subject to the Federal Rule.

1. If your practice places amalgam, only pre-capsulated single-use capsules may be used.
2. All chair side traps, and vacuum pumps must be maintained according to manufacturer's recommendations.
3. All filters, screens, traps and collection containers shall not be rinsed over or into a sink. Amalgam waste should never be put down the drain.
4. Staff should be trained in the proper handling and disposal of amalgam waste.
5. Only non-oxidizing, non-chlorinated disinfectants and neutral line cleaners may be used when cleaning suction lines. Evacuation line cleaners must not have a pH less than 6 or greater than 8.
6. Used amalgam capsules, scrap amalgam, removed teeth containing amalgam and any other contact and non-contact amalgam shall be collected and stored in an appropriately labeled and tightly sealed container in preparation for proper disposal or recycling.
7. Any bulk amalgam must be recycled by sending waste to an offsite recycling facility.

Recordkeeping Requirements and Retention

A copy of the Initial Compliance Report shall be kept onsite until your office is closed, moves to a new location, or ownership is transferred. This Initial Compliance Report must be made available to City of Fort Collins IP staff upon request.

To ensure adherence to both federal and local Dental Amalgam Control Programs, the following documentation should be maintained for a minimum of three (3) years. These documents can be stored either in physical or electronic form.

1. Documentation related to inspections of amalgam separators including dates, person performing inspections and results of inspections.
2. Documentation of when amalgam retaining containers or equivalent have been replaced.
3. Documentation, including dates and facilities, of when and where amalgam is picked up or shipped for proper disposal recycled.
4. Documentation related to any repair or replacement of an amalgam separator, include make and model.
5. Manufacturers operating manual for current device installed.
6. Annual certifications sent out by the City of Fort Collins IP Department

Maintenance and Operational Logs

The following are actions that will need to be logged by each dental facility subject to the Federal Rule.

1. Amalgam separator inspections
 - a. Inspections should verify that the equipment continues to operate as designed and should note the estimated fill level of the collection container.
 - b. Inspections should also verify that the expiration date of the collection container has not passed. Amalgam separator manufacturers set expiration dates for their collection containers to ensure proper operations.
2. Amalgam separator maintenance
 - a. Log entries should include when collection containers are ordered and changed by staff.
 - b. Log entries should note if unplanned maintenance needs were found during inspections and what actions were taken to follow up.
 - c. The destination of waste should be included.

Compliance Schedule

Federal regulations require existing dental facilities to comply with applicable obligations by July 14, 2020. New dental facilities must comply immediately according to the Rule. However, City of Fort Collins City Code [Section 26-340(e)] does not differentiate between new and existing dental facilities; all dental facilities that place or remove amalgam are required to have an ISO 11143 certified amalgam separator in place and follow outlined Best Management Practices.

Exemptions

1. Dental facilities that do not place amalgam and remove amalgam in less than 5% of the procedures performed will not be required under federal regulations to install an amalgam separator.
 - a. Each office certifying that no amalgam is placed at their facility is subject to inspection, to verify that exemption is appropriate.

If you have any questions, please contact the City of Fort Collins Industrial Pretreatment Department at 970-221-6938 or rbarton@fcgov.com.