Minnesota Amalgam Separator Approval Procedure
April 20, 2012

Introduction

Since 2003, Metropolitan Council Environmental Services (MCES), in partnership with the Minnesota Dental Association (MDA), has administered an Amalgam Recovery Program in the Minneapolis – St. Paul Metropolitan Area. The MCES/MDA program has included a process for approving amalgam separators for installation by dentists. Approved separators must meet certain technical and performance criteria as determined by testing laboratories and certification bodies that meet certain qualification criteria.

In 2007 the Minnesota Pollution Control Agency (MPCA) and the Minnesota Dental Association signed a Memorandum of Understanding “…for the Statewide Reduction of Mercury from Dental Practices.” The MOU identifies several responsibilities for the MPCA, including the responsibility “…to establish criteria and a process to identify approved amalgam separator models which considers wastewater flow rates and treatment effectiveness.” The MPCA has consulted with MCES and the MDA and has reviewed separator approval criteria and programs nationwide, including the ISO 11143 Standard and the associated testing and certification processes. Based on this review and consultation, the MPCA has adopted updated criteria (Part 1 below) and an updated process (Part 2 below) for approving separators for installation and use statewide.

As noted above, MCES and the MDA have maintained a list of separator models meeting certain approval criteria. However, there are no models on the current MCES/MDA list of approved amalgam separators that meet the updated state-wide approval criteria below. For this reason, all separator models on the MCES/MDA list must be retested in order to be included on what will become an updated statewide list of approved separators (see Part 2, below). The deadline for submission of test reports and certificates will be 12 months from adoption of the criteria. Separator manufacturers that do not meet this deadline will not have their models included on the updated statewide list. This updated statewide list will supersede the current list of approved models compiled for the MCES service area. The 12 month period will serve as a transitional phase from the existing MCES/MDA listing procedure to the updated statewide approach.

Part 2 below describes the retesting and recertification process that will take place during the 12 month transitional period. MCES has significant technical expertise with amalgam separators and the ISO 11143 testing and certification processes. Therefore, on behalf of the MPCA, MCES will provide technical review and analysis of separator test reports and certificates submitted by manufacturers for inclusion on the MPCA’s updated statewide list of approved separators.
**Part 1. Criteria for Amalgam Separator Approval and Listing**

To be included on the list of approved separators in Minnesota, a separator must:

1. Pass the current ANSI/ADA Specification No. 108 (see note below) for evaluating amalgam separators at a flow rate of at least 1 liter/minute (i.e., the tested “maximum flow rate”).

2. Meet a minimum removal efficiency of 99% when tested according to the procedures in ANSI/ADA Specification No. 108, based on the overall arithmetic average of the three “empty” and the three “simulated full” test results.

3. Be tested by a testing laboratory that is accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation’s Mutual Recognition Arrangement (see: www.ilac.org). The testing laboratory’s scope of accreditation must include ISO 11143.

4. Be certified by a certification body that is accredited by an accreditation body that is a signatory to the International Accreditation Forum’s Multilateral Recognition Arrangement (see: www.iaf.nu).

5. Separators must display a certification test mark from the certification body.

6. Separators must display the overall arithmetic average removal efficiency percentage as required and determined in Criterion 2, above, for the corresponding maximum tested flow rate employed during the test.


**Part 2. Amalgam Separator Retesting and Relisting Process**

Separator manufacturers who have approved separator models on the current MCES/MDA list (“current manufacturers”) will be given 12 months to complete retesting. Milestone dates are:

**Adoption Date:**
This is the time at which the new criteria are adopted and the 12 month retesting period begins. Shortly before this date, the MPCA will notify current separator manufacturers of the new approval criteria, the requirement to have their separator model(s) retested, and the plan that an updated statewide list of approved separator models will be published at the end of the 12 month period. Separator manufacturers that are known to MPCA and MCES, but who do not have an approved separator on the current list (“other manufacturers”), will also be informed.
12 months:
By the end of the 12 month period, manufacturers must submit new test reports and certificates to MPCA and MCES that demonstrate that they meet or exceed the criteria listed in Part 1 above. Based on the reports and certificates submitted, an updated list of approved amalgam separators will be compiled by MPCA and posted/published. This list will include models where current or other manufacturers have submitted a laboratory test report and certificate for their model(s), demonstrating that they meet the approval criteria in Part 1 above.

Additions to the existing list of approved separator models from current or other manufacturers:
If a current or other manufacturer submits a test report and a certificate for a new model during or after the 12 month retesting period, satisfying the approval criteria, then that new model will be added to the updated statewide list.

Part 3: Existing and new separators: All separators must be on the list of approved separators in effect on the date of installation or reinstallation.

In order to meet the MPCA’s statewide Separator Approval Procedure and qualify for installation or reinstallation in the state, amalgam separators must be included on the list of approved models in effect at the time of installation or reinstallation. MPCA, with technical support from MCES, will maintain a list of separator models that meet the statewide separator approval criteria (Part 1, above). The list will be posted on the website of or otherwise available from MPCA. Existing installed separator models that were on the approved separator list at the time of installation (or reinstallation) may remain in service even if that model does not qualify for approval, listing, and installation at a later date. When a new list is posted, all new separator installations and reinstallations must be models included on the list that is in effect on the date of installation or reinstallation, and must be appropriately sized. Existing separators may not be removed from service and reinstalled in expanded or remodeled clinics if they are not on the list in effect on the date they would be reinstalled.