

NACWA Pretreatment and Pollution Prevention Workshop

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Proposal for a National Review Committee for Evaluating & Listing Amalgam Separators

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Please have a seat



Dental Loading Modeling Study Commissioned by the ADA:

Estimated that 6.5 tons mercury are released to WWTPs annually by 133,059 general practice dentists and specialists using or removing amalgam in the US.
(Vandeven & McGinnis, 2005)

$$6.5 \text{ tons/year} = 13,000 \text{ pounds/year} = 5896 \text{ Kg/year}$$

$$5,896,000,000 \text{ mg/year}$$

$$(133,059 \text{ dentists})(48 \text{ weeks/yr})(4 \text{ days/wk})$$

$$= 231 \text{ mg Hg / dentist / operating day}$$

Equates to 53% of mercury to WWTPs coming from dentists.

Two fundamental reasons
why we would consider a
National Review Committee:

*Difficult to sample & analyze
wastewater, and*

Too many dental clinics !

Sampling
under
vacuum

MCES/MDA
2001 Study



All
wastewater
collected



MCES

8/4/2006 16:37



Recruiters solicit young patients for North Texas dentists







“Big Shift” from compliance based on wastewater sampling to amalgam separator “Bench-Top” testing. (such as ISO or ANSI testing)

This leads to:

Use of the Conformity Assessment Process

3 Parties involved, and what their position is:

1st Manufacturer: “My separator is good”

2nd Customer: “What I buy is good”

3rd Independent lab & certification body: “We’ll check”

3rd Party – Lab and Certification Body

The lab and the certification body (CB) are independent of the manufacturer and the customer.

A lab tests the separator and a CB sets up a “quality control procedure” with the manufacturer to ensure and assess that the product *conforms* to the ISO Standard or ANSI Spec.

Hence: The Conformity Assessment process

Certification is a separate function than lab testing

Examples of CBs include:

UL, NSF, SP (Sweden) and TÜV NORD (Germany)

How Are You Going To Administer An Amalgam Separator Program ?

Most use the ISO Standard

Now use: ANSI - ADA Specification 108

ANSI is the US' member to ISO (www.ansi.org)
American National Standards Institute

KEY POINT, NEITHER:

ANSI or ISO oversee the testing labs

ANSI has delegated administrative responsibilities for US standards activities to the American Dental Assoc. (ADA)

Fairness & Gate-Keeper Issues

If the regulator approves and/or lists separator models, then the regulator is acting as a “Gate-Keeper” in terms of who can sell in their jurisdiction.

If sales are based on lab testing,
If there are 125,000 general practice clinics in the US,
And If a separator costs \$1000:

Then the value of a test report is potentially:

$$\$1000 \times 125,000 = \$125,000,000$$

Plus, there will be ongoing filter and cartridge revenues.

Questions by POTWs or States Setting Up Amalgam Separator Programs

What is a good amalgam separator?

Should I require separators be ANSI Spec. tested?

Should I require Certification?

Am I supposed to be an expert on the ANSI Specification,
on testing, reviewing lab reports, certification, and CBs?

If I require or ask for separators, but do not tell dentists which
separators are acceptable, will they think anything is alright?

Is my silence interpreted as “approval”?

Questions by a POTW or State, (cont.)

Do the hydraulic test data for a flow restrictor make sense?

Will I copy a programs' list of approved separators without doing my own homework or checking with them (in case there are any concerns or lessons to be learned)?

What do I do if I accept a model, then the mfg changes it?

How do I know if a lab or a certification body (CB) is good?

Should I accept lab reports and certificates from anyone?

Who evaluates the labs and the CBs?

Who evaluates those that evaluate the labs and CBs?





Questions by a POTW or State, (cont.)

Will I be presented with lab reports or certificates (from a mfg) that have been rejected by another regulator?

What if I get varying lab reports on what I think is the same model?

Will I have to resolve complaints, lodged by a competitor, in terms of how I handle another manufacturer?

What if I need to remove a model from a list?

Will I be threatened with legal action by a manufacturer?

So - What Is A Possible Answer ?

Set up a Committee at a national level to:

Review the Conformity Assessment processes

Evaluate testing laboratories

Evaluate certification bodies

Identify acceptable labs and certification bodies

Review test reports and certificates

Issue findings on separator models

Benefits to POTWs & States using a National Review Committee and Separator Certification

Reduce regulators' work of establishing a separator program

Minimize or eliminate burden of reviewing test reports

Minimize or eliminate compiling a list of approved separators

Separators displaying a test “mark” will allow regulators to confirm that a separator has been certified.

Certification Body (not the POTW or state) would address issue of separator models being modified by mfgs and other problems that may arise with testing or use of the test “mark”

Ideal Amalgam Separator Certification Program

First, regulators need to require that separators be “Certified”

Then, establish a uniform certification system with criteria to be met by all of the various certification bodies

Testing laboratories and certification bodies are accredited and their “Scope of Accreditation” includes ISO 11143

Testing laboratories, certification bodies, and accreditation bodies (AB) follow applicable ISO Guides and Standards (ISO Guide 65 and ISO Standards 17025 & 17011)

ABs are full members of ILAC (testing) and IAF (certification)
See: www.ilac.org and www.iaf.nu

Benefits to all by using a National Review Committee and a Uniform Certification System

Separator manufacturers would not need to work with each POTW and state to get their separator models listed

Avoids “midcourse” corrections while administering program if implementation of Committee precedes local program start-up

Dental supply companies (who often market for the manufacturers) would be able to sell across multiple POTW service areas and states

Work toward International Accreditation Forum (IAF) goal of:
“Certified Once – Accepted Everywhere”

National Review Committee and Uniform Certification System (continued)

Doable by regulators working with certification bodies

All basic tools are already in place:

Testing, Certification, and Accreditation

National Review Committee could:

Establish some specific certification criteria,
Review certified separators meeting the criteria, and
Allow market to respond.

*RESULT: Good, Complete, Fair Program;
Where all involved understand expectations.*

International Accreditation Service, Inc.

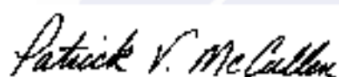
CERTIFICATE OF ACCREDITATION

This is to signify that

NSF INTERNATIONAL
789 NORTH DIXBORO ROAD
ANN ARBOR, MICHIGAN 48105
(Revised July 1, 2007)

Testing Laboratory TL-179

has demonstrated compliance with ANSI/ISO/IEC Standard 17025:2005, *General criteria for the competence of testing and calibration laboratories*, and has been accredited, commencing April 3, 2006, for the test methods listed in the approved scope of accreditation.



Patrick V. McCullen
Vice President



C. P. Ramani, P.E.
President

(see attached scope of accreditation for fields of testing and accredited test methods)

This accreditation certificate supersedes any IAS accreditation certificate bearing an earlier date. The certificate becomes invalid upon suspension, cancellation, revocation, or expiration of accreditation. See the *IAS Accreditation Listings* on the web at www.iasonline.org for current accreditation information, or contact IAS directly at (562) 699-0541. Print Date: 07/17/2007

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International Accreditation Service, Inc.

SCOPE OF ACCREDITATION

NSF International TL-179
(Revised July 1, 2007)

NSF International
789 N. Dixboro Road
Ann Arbor, MI 48105

Craig Morr
Quality Assurance & Org. Safety
(734) 769-8010

FIELDS OF TESTING	ACCREDITED TEST METHODS
Plastic pipe and pipe fitting	ASTM Standards D 1784, D 1785, D 2235, D 2239, D 2241, D 2464, D 2466, D 2467, D 2564, D 2609, D 2661, D 2662, D 2665, D 2666, D 2672, D 2751, D 2846, D 3034, D 3309, D 3310, F 409, F438, F 439, F 441, F 480, F 493, F 628, F 656, F 789, F 877, F 891 and F 949, and NSF Standards 14 and 61
Water testing for contamination	BS Standard 6920
Dental equipment	ISO Standard 11143

April 3, 2006
Commencement Date



C. P. Ramani, P.E.
President

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International Accreditation Series

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Environmental Council of the States (ECOS) and the Quicksilver Caucus Resolution:

Urging Creation of a Dental Amalgam Separator National Review Committee

Benefits:

Avoid duplication of effort by cities, counties, states, & manufacturers,
Save money otherwise spent by cities, counties, & states,
ADA recommends ISO 11143 compliant separators,
Reduce mercury from likely largest contributor (dental),
Take advantage of the tools of the voluntary: “Conformity Assessment
Process” (testing, certification, & accreditation)
Avoid problems encountered by cities, counties, & states.

ECOS Resolution: 11-3, September 2011



