(July 21, 2005) Note to reader: The following text is a copy of what the United States has sent in to ISO as part of the US' input on the revision of the ISO 11143 Standard for testing amalgam separators. This text makes up the "Additional Comments and the Data", that supplement the main submittal sent in by the US which is referred to as the "template" (sent in around the time of July 1, 2005). The template gives comments and suggested revisions to the specific language within the Committee Draft. (The template is a piece that may not be shared outside of the group working on the revision.)

The following includes general and specific comments on the Committee Draft for the ISO 11143 Standard and a report on the quantities and flowrates of dental clinic wastewater. The US' "Template for comments and secretariat observations" refers to additional comments and data. These comments and data are included here.

General US Comments

Data has been reviewed dealing with the use of the 1,2 µm filter (N 217) and the possible elimination of either the "empty" or the "full" test condition (N 218). The N 385 Committee Draft (CD) is written without the use of the 1,2 µm filter, while the US supports using this filter. The US also supports using both the empty and the full test conditions.

The fundamental problem with using the data from N 217 & N218 is that the results are from amalgam separators that already pass the efficiency test of the 11143 Standard. These model separators function efficiently enough to remove amalgam in both the empty and the full modes. They also remove amalgam across the broad range of the particle size distribution that has been set for testing separators. Since the purpose of the standard is to evaluate a wide range of types and models and to distinguish between the separators that pass and those do not pass, it does not seem prudent to look at data for only those models that pass.

The models that have not passed ISO 11143 may not be as efficient at removing the smallest particles. If this is the case, testing these models would result in more particles being caught on the 1.2 µm filter than was presented in N 217. Therefore, the difference between the "with" and "without" values would be greater than the data presented in N 217.

If the 1.2 µm filter is dropped, the effect will be that the separators will be given "automatic credit" for having removed the smallest particles, even though they were not actually captured by the separator. While some countries are calling for the elimination of the larger particles from the particle size distribution, we should not overlook the smallest particles. At least one country is even suggesting that colloidal and dissolved mercury be part of the Standard to evaluate separators.

With regard to the empty and full test conditions, some separator models that have not passed the 11143 Standard may have had problems operating efficiently either empty or full. We may not have the chance to see such data, since this may be "research & development" type data that only the separator manufacturers see. Again, it does not seem prudent to completely drop one of the test conditions without seeing all data. The comments presented here are not meant to suggest that the ISO 11143 Standard could or should be modified to drop either the empty or the full test condition.

The complexity of existing separators is too great to be able to determine ahead of time (before testing) which test condition could be dropped, or to say, which is the “worst case” or which is not the worst case test condition. Also, with no formal independent analysis of each separator model, how would questions be resolved either before or after testing, as to whether a separator should have been tested using the “other” test condition?

After reviewing the N 218 data showing results for both empty and full testing, a case can easily be made for keeping both of the two test conditions. Looking at the 2001 data, the A1000 performed “worst” empty, while other model separators that may initially seem to be similar (e.g., MSS 2000, Rasch 890-4000, & RME 2000) had “worst” data when tested full. Also, the Amalgam Collector CE12 is a sedimentation Type 2 separator, which is to be tested full as its “worst case” under the Committee Draft. Yet it performed “worst” when tested empty. The data presented in N 218 did not show a clear pattern that would indicate which test condition could be dropped

Looking at the 2004 data in N 218, it should be noted that the ECO II performed “worst” empty by half a percentage point when compared to full. According to the Committee Draft, it should be “worst” when tested full, as it did when reported in the 2001 data. The 2004 outcome went against what was expected, but more importantly, the outcome was opposite the 2001 data. Also looking at the 2004 data, the Hg5 performed “worst” full, while its bigger version, the Hg5HV performed “worst” empty by a full percentage point. One would expect that given the similarity of these two separators their “worst case” testing would be the same – but they are not.

Therefore, it is our position that both the empty and the full test conditions should be retained. The 11143 Standard should be returned to its original (1999) method of testing with both of these two test conditions.

Both of these possible changes (dropping the 1.2 µm filter and one of the two test conditions) move the ISO Standard further away from reflecting the true nature of dental clinic wastewater and the conditions under which separators need to operate. The US contends that there should be adequate justification provided for making such changes, such as data on the amount of time or money saved if these modifications to the Standard are implemented. If these modifications are suggested to make testing easier and less expensive it is important to do this analysis.

Specific Comments

N 217
Issue of conducting the test without the use of the 1.2 µm filter. ISO Clause 7.1.8.

The US is opposed to dropping the 1.2 µm filter from the 11143 Standard.

The first working draft dated November 8, 2004 (N 220) shows the 1.2 µm filter deleted from the text of the standard. This leaves the 12 µm and the 3 µm filters in the standard. Apparently, removing the smallest (tightest) filter is meant to make conducting the test easier and quicker.

As we understand it, the test sample may contain particles smaller than 3 µm. It should be noted that if the set of filters (in the ISO Standard, Clause 7.1.8) do not catch this fraction of the test sample it will not show up in the weighing process. It will then be assumed that the amalgam separator has retained this fraction of the original amalgam sample (the starting sample weight minus the weight caught on filters equals the weight retained by the separator).

In the ADA's 2001 data, there are instances where the deletion of the 1.2 µm filter results in increasing the removal efficiency by basically a full percentage point. Please see the 2001 test results for the BullfroHg and the Durr 7800. If the difference in the test results with or without the 1.2 µm filter were to account for the difference between 94% and 95%, then the elimination of the 1.2 µm filter would have a strong bearing on the overall efficiency reported for these products.

The US is opposed to dropping the 1.2 µm filter from the 11143 Standard. Without the 1.2 µm filter the ISO Standard is less of a reflection of the actual characteristics of dental clinic wastewater. If there are changes to the Standard, it should be done to move toward reflecting the true nature of dental clinic wastewater, not a move away from reflecting the nature of clinic wastewater. An example of a more appropriate modification of the amalgam sample would be the elimination of the larger particles (e.g., fraction 1) from the Standard.

N 218
Issue of dropping one of the test conditions, either the "empty" of the "full" condition.

(Affecting Clauses: 9.3.2.9, 9.3.2.10, and 9.4.2. in the Working Draft N 220)

The US suggests that both the "empty" and the "full" test condition be kept as part of the ISO Standard.

This position is based on the following reasons:

(1) The data presented by the ADA shows no pattern as to which test condition should be eliminated. Some data indicate that separators perform better full, whereas some data indicate that separators perform better empty. Therefore, we are uncertain as to how one can suggest which test condition should be dropped. Based on common engineering principals it can be expected that some separators may perform better full (like a classic filter that removes more as it loads up) as opposed to a separator with reduced settling capacity (resulting in more turbulence) as it loads up.

(2) If the “full condition” is dropped, how is a separator manufacture’s indication or determination of a full separator to be checked by a testing laboratory? If a simulated full separator is not tested, a manufacturer may be able to show any level they desire as being full. See Clause 3.5 of the Standard dealing with the maximum filling level, where it states: “level defined by the maximum collecting capacity of the collecting container of the amalgam separator at which the efficiency is unaffected”. If the full condition is dropped, how will it be known that the “efficiency is unaffected”? Clauses 3.7, 3.8, and 3.9 also deal with the maximum filling level and the efficiency of the separator.

(3) The 2001 ADA data for the Durr 7800 and the MSS 2000 shows a difference of approximately 1 percentage point. If this was a variation between 95% and 94%, and if the “full” condition were dropped, it would mean a difference of passing or failing the ISO test. Earlier RWTÜV data on file for a particular separator showed a similar result. Both values were above 95%, but they differed by approximately 1 percentage point, which would have a bearing on passing or failing if the results were between 95% and 94% and if one of the test conditions were dropped.

(4) Even if all of the available data on separators showed similar efficiency results today (which they do not either in numeric terms or as being consistently better either empty or full), how are we to know if separators in the future won’t have significantly different operating characteristics?

Report on Dental Clinic Wastewater – Quantities and Flowrates
Sizing Amalgam Separators

This report compiles information related to the hydraulic characteristics of dental clinic wastewater and amalgam separators designed to treat such wastewater. The goal of this report is to understand the generation of clinic wastewater, primarily from the standpoint of:
(1) maximum flows generated in clinics, (2) amalgam separator capabilities to treat at maximum flowrates, and (3) the ISO test procedure calling for *maximum flowrates as specified by the amalgam separator manufacturer*".

The sections of this report are:

(1) What vacuum pump manufacturers call for regarding flushing a vacuum system
(2) How are separators tested, operated, and set up with flow restrictors
(3) Table of vacuum system flushing quantities for dental clinics
(4) Table of vacuum system flushing volumes and rates for dental clinics
(5) Notes from a meeting with dental supply companies on vacuum system flushing
(6) A report by RAMVAC on the time required for RAMVAC air/water separating tanks to drain

(1) What vacuum pump manufacturers call for regarding flushing a vacuum system:

Vacuum Pump Manufacturer	**Flushing per operatory, Per/Day:**
RAMVAC	1 ¾ quarts (1.7 liter)
Air Techniques	1 liter
Den-Tal-EZ Custom Vac	1 quart (~ 1 liter)

(based on operation and maintenance manuals)

(2) How are separators tested, operated, and set up with flow restrictors?

Model **Installation Location**	**ISO Test Flowrate, L/minute**	**Flow Restrictor In Place?**	**Surge Tank Capacity, Liters**	**Can Separator Overflow, and Bypass Treatment?**
Chairside				
Asdex AS-9	0.5	Restricts as it loads	0	No
Central				
SolmeteX Hg5	0.05	No	4.6	Yes
Rebec 2000 Catch Hg	1.0	Yes	19	Yes
MSS 1000	1.0	Yes	11	Yes
MSS 2000	2.5	Yes	22	Yes
ECO II	3.0	No	0	No
Central – Below A/W Separator Tank in Turbine (Dry) Vacuum System				
Guardian Amalgam Collector	3.0	Yes	0†	No
ECO II	3.0	No	0†	No
Rasch 890-6000/4500 (2-stage sys.)	4.0	*	0†	No
Durr 7800/7801	12.0	No	0†	No
Central – After Liquid-Ring Pump				
Rasch 890-1000/4000 (2-stage sys.)	4.0	*	0	Yes
Durr 7800/7801	12.0	No	0	No

* A restrictor is available

† The air/water separator tank may act as a surge tank during the day, as this tank fills up. When the vacuum pump is turned off, the contents of the air/water separator tank will flow to the amalgam separator.

(Other models exist that are not listed in this table, such as those that operate in a "batch treatment" mode; where wastewater settles overnight, then is decanted.)

(3) Table of vacuum system flushing quantities for dental clinics.

Information gathered during the initial stages of setting up a study of amalgam separators and loadings from dental clinics, in the Minneapolis & St. Paul metropolitan area of Minnesota. Data is from November 1998 questionnaires to give an idea of the amount of the cleaning solution used to flush clinic vacuum systems.

Clinic	**Flush Quantity**	**Chairs Dent./Hyg.**	**Flush Quantity Per chair, Per Event**
1	1 quart/chair/day	4 – 3	1 quart
2	1 gal/chair/Wednesday 1 gal/chair/Friday (plus rinse between patients)	2 – 1	4 quarts
3	1 gal/chair/day	2 – 0	4 quarts
4	4 quarts/day for the operatories used	5 - 3	Approx. 0.5 +
5	2 times/week, plus after extractions 6 gallons/week	3 – 1	Approx. 0.75 quarts
6	2 gallons/week, flushed weekly	4 – 3	1.1 quarts
7	1 gallon/chair, once/week	1 – 1	4 quarts
8	Flush daily, use 2 gallons/week	1 – 1	if 4 days: 1 quart if 5 days: 0.8 quarts
9	Flush daily, use at least 10 gallons.	3 – 2	if 5 days: 1.6 quarts if 4 days: 2 quarts
10	Flush once/week, use 1 gallon	2 – 1	1.3 quarts
11	Flush daily, use 30 gallons/week	6 – 2	if 5 days: 3 quarts if 4 days: 3.75 quarts
12	Flush daily, use 5 gallons/week (works 4.5 days/week)	2 – 2	1 quart
13	2-3 quarts/day	2 – 1	0.67 – 1 quart
14	About 1 gallon/unit (X 6)/day (some days not all rooms used)	3 – 3	4 quarts
15	Flush daily; use approx. 10-15 gal/wk If 2-3 gal/chair/wk, if 5 days/week, Then 1.6 – 2.4 quarts/chair/day	2 – 3	if 5 days: 1.6 – 2.4 quarts
16	2 quarts/chair/day (4 days/wk) (plus possibly more)	2 – 1	2 quarts
17	Once/week, 4 gallons	2 – 2	4 quarts
18	After each patient. 10 quarts/week	2 – 3	

19	Flush weekly, use 1 gallon/operatory	2 – 2	4 quarts
20	Flush weekly, 4 gallons	2 – 1	5.3 quarts
21	Flush weekly, 1 gallon/room	4 – 1	4 quarts
22	Estimate 1.1 quarts/day/chair	7 – 4	1.1

(4) Table of vacuum system flushing volumes and rates for dental clinics.

The table below gives data from surveys completed during a meeting of dental assistants held on March 4, 2004, in St. Paul Minnesota.

Clinic Number	Regular chairs + Hygiene chairs	Flushing Frequency	Volume of flush/chair (quarts)	Time spent to flush each chair (minutes)	Flowrate (qrts/min)	Comments
1	3 + 2	Daily	1	< 2	> 0.5	Additional flushing after "bloody" patients or use or prophy paste
2	4 + 2	Weekly (reg chairs) Daily (Hyg chairs)	4 each type of chair	3 – 5	0.8 - 1.3	
3	2 + 1	Daily	4	4	1.0	
4	4 + 4	After each patient	1 Multiple chairs are flushed at same time	1	2.0 + 2.0 or greater depending on how many chairs are flushed at once	
5	3 + 2	Daily	0.8 quarts (1 gallon of cleaning solution for 5 chairs.) Then 4 quarts of hot water per chair.	1-minute for cleaning solution 2 – 5 minutes	0.8 cleaning solution 0.8 – 2.0 hot water	Additional flushing occurs throughout day
6	2 + 0	Weekly	4	5	0.8	

(5) Notes from a meeting with dental supply companies on vacuum system flushing.

April 14, 2003 meeting with representatives from four dental supply companies and Metropolitan Council Environmental Services in St. Paul Minnesota:

Representatives were asked about how they thought clinic staff flushed their vacuum system, such as how much cleaning solution is used, and how long it takes staff to flush each operatory:

Responses:

- Use a bucket, or some kind of container to bring the cleaning solution to the operatories.
  Some flush all (operatories) at once.
  Use a quart, or up to a gallon or two at once.
  If there are problems, they flush with more water.

- Take a maximum of 2 minutes.
  Use about a gallon per operatory. 2 minutes.

- Flush for 2 minutes, with a couple minutes in between operatories.
  Use a quart or two.

- Mass inconsistency.
  Some stick a hose in a sink. (See comment below*.)

- 1 gallon per operatory, taking 2-3 minutes.

- What if all chairs are flushed at once? What then?

- Why don't you come up with standard criteria (flowrate) for testing amalgam separators?

*July 14, 2003 phone call with Dr. Robert A. Meyer (President, RAMVAC, a dental clinic vacuum system manufacturer) regarding flow. He stated that:

"Clinic staff don't know how much can be drawn up by a vacuum, through a 'high volume evacuator'.
A pump can pull a gallon in 30 seconds through the HVE."

(6) A report by RAMVAC on the time required for RAMVAC air/water separating tanks to drain.

Submitted to Metropolitan Council Environmental Services, St. Paul, Minnesota (July 22, 2003)

Objective

The objective of this test by RAMVAC was to determine the actual capacity and the drain times for RAMVAC's 15, 30, and 50-gallon air/water separator tanks.

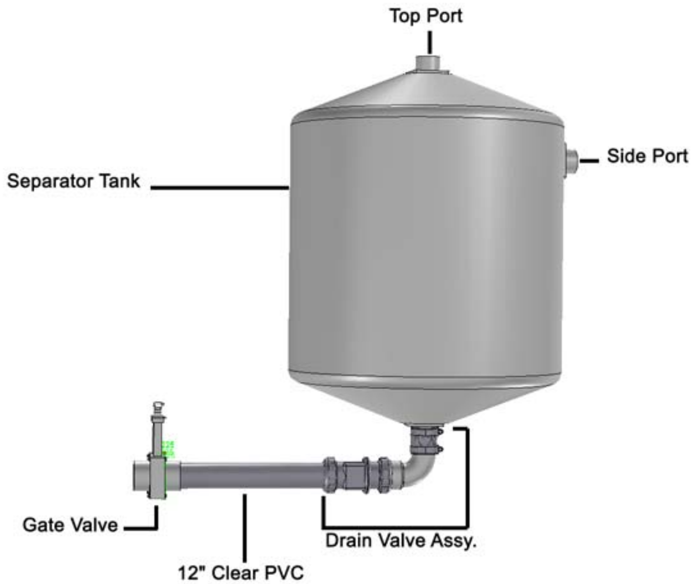
Results Summary		15-Gallon Box Tank	30-Gallon Cylindrical Tank	50-Gallon Cylindrical Tank
Tank Capacity		17 gallons	27 gallons	49 gallons
Tanks filled to Capacity		64 Liters	102 Liters	185 Liters
Fastest Drain Time	○ Both Ports Open ○ 2-HVE sized holes (5/16" diameter) open ○ Larger hole or more holes did not decrease drain time	40 sec 96 L/min	45 sec 136 L/min	65 sec 170 L/min
	○ 1-HVE sized holes (5/16" diameter) open	50 sec 76 L/min	53 sec 115 L/min	83 sec 133 L/min
	○ 3/16" diameter hole in one cap ○ Second port capped (closed)		1.65 min	2.56 min
Slowest Drain Time	○ 1/8" diameter hole in one cap ○ Second port capped (closed)	3.91 min 16 L/min	3.76 min 27 L/min	6.0 min 30 L/min
	○ Both ports capped (closed)		Drained ¼ to ½ gallons only	

MCES comment:

"Looking at the 'Slowest Drain Time', and even at a fraction of the volume, yet with the same amount of time to drain, the flowrate of the wastewater leaving the air/water separator tank would be significant."

Example of a RAMVAC air/water separator tank used in a turbine (“dry”) vacuum system.

Wastewater and solids collect in such a tank, and do not drain out until the vacuum pump is turned off. When the pump is off, the drain valve (“flapper” valve) opens up, allowing the contents of the tank to drain out. (The gate valve was in place as part of this study; it is not used in an actual dental clinic setting.)



Test conducted by RAMVAC:

Test Set-Up

The test system included:

- RAMVAC Separating Tank
- RAMVAC tank drain valve assembly
- 12 inch length of clear tubing
- Gate valve

Test Procedures

The tank was drained with several vent configurations:

- Both top ports (15-gallon tank) or top and side ports (cylindrical tanks) open
- 1, 2, and 3 HVE sized (5/16”) holes in the cap on one cap (the second cap was not penetrated)
- 3/16” hole in one cap (the second cap was not penetrated)
- 1/8” hole in one cap (the second cap was not penetrated)
- Both ports capped (closed)

Conclusions

- Leaving two HVEs open will allow the tanks to drain at their fastest rate.
- New plumbing systems with minimal to no leakage will drain slowly if nothing is opened to vent the system.
- It is possible for the tanks to create enough vacuum by draining water to close the check valve and stop draining completely if the system is sealed off.
- The 15-gallon box tank drain times were slightly longer than the 30-gallon cylindrical tank. This is attributed to the greater pressure due to the greater height of the 30-gallon tank.
- Venting is suggested to ensure tanks drain quickly and completely.