Environmental Protection Agency

Public Hearing on
Effluent Limitation Guidelines and Standards for the Dental Category

1:00 p.m. to 2:05 p.m.

Monday, November 10, 2014

EPA East Building

Room A

1201 Constitution Avenue, N.W.

Washington, D.C. 20210

EPA PANEL:

ERIC STRASSLER, Chair; EPA

ROBERT WOOD, EPA

DAMON HIGHSMITH, EPA

JAN MATUSZKO, EPA

C O N T E N T S

IN ATTENDANCE:

ANDREW COATS, LIBERTY PARTNERS GROUP

MARK FRAMPTON

BRAD DOWNS, STERISIL

TARANGA GUPTA, RIVIERA

KELLY BEAUREGARD, SOLMETEX

IN ATTENDANCE (Continued):

ROBERT RAIBLE, AMERICAN DENTAL ASSOCIATION

ALLEN KLUMP, CONGRESSMAN JEFF DUNCAN

KAREN MILAM, EPA

RYAN MADDEN

DEANNA B. FRAKER, R&D SERVICE AMALGAM SEPARATORS

NATALIE PACINI

JEFF TROUPE

ROBERT J. BURNS

LAUREN NAGEL

HAROLD CHASE

CYNTHIA FINLEY

P R O C E E D I N G S

[Whereupon the hearing commenced at 1:03 p.m.]

MR. WOOD: Good afternoon everybody, thanks for coming. My name is Rob Wood and I'm the director of the engineering and analysis division at the Office of Science and Technology at the EPA's Office of Water. We are the division that is responsible for the proposed rulemaking that we are here to talk about and hear from you on today.

There are a few people that I would like to introduce, Eric Strassler, to my far right, is going to make sure that we stay on track today and that I don't forget to do anything in the hearing today.

Damon Highsmith to my right is a professional staff in the Engineering and Analysis Division and Damon is the lead project manager, if you will on the dental category of pretreatment standards proposal that we are here to talk about.

And Jan Matuszko to my left is the chief

of the Engineering and Analytical Support branch in my division and is the managing branch chief on this rule, and we have got a few other EPA folks in the room who, I will wave to you or something as we go.

Again, thanks for your interest in the proposed rule. We are, what was the actual proposal date?

MR. STRASSLER: October --

MR. WOOD: October 22nd. Of course it would be there in front of me.

So, I presume everybody here is familiar with the rule. We do not plan to do a presentation on it today, rather, this is an opportunity to hear from you. So, we are going to allot five minutes of time to registered speakers. We are not that pressed for time, so if you really feel like you need more, just signal and we will manage the time as best we can.

There will be a transcript of today's hearing included in the rulemaking record. And, of

course, if you are here to listen and you don't wish to speak and you have comments that you want to make on the proposed standards, we urge you to submit those comments in writing, and we will handle those as we would any other public comments, which will all be available -- the responses will be available as well in the docket for the rulemaking.

The comment period is currently set at a 60 day public comment period counting from October, 22nd and we have a request -- several parties have requested an extension to that comment period which we are currently considering, and we will post on our website where all the current information in the dental category, the Clean Water Act rulemaking is located -- what we decide to do with that request for an extension.

Okay, so, with that, I think I am going to turn it over to Eric to get things started, and before we kick off with the first speaker, if there are any questions about how we are going to proceed,

feel free to ask.

Okay, Eric.

MR. STRASSLER: Okay, thank you Rob. Good afternoon, a couple of administrative items, restrooms are outside in the lobby by the security desk. If you need to use those, please ask one of the staff to point you to the restrooms. And if you have any cell phones or any other gadgets that make noise, please put them on vibrate or turn them off. Thank you.

Okay, we are going to go in the order in which we were notified that you want to testify. When you step up to the lectern please state your name and any organization you are affiliated with, if any.

First is Carter Brown.

MR. BROWN: Thank you so much, it's great to have an opportunity to be here. I am Carter Brown, the president of the Academy of General Dentistry, and also a practicing dentist in South Carolina. The Environmental Protection Agency, the EPA has proposed technology-based

pretreatment standards under the Clean Water Act for discharges of pollutants in publicly owned treatment works, or POTWs, from existing or new practices that discharge amalgam.

And specifically, the proposed rule requires dentist to use amalgam separators and best management practices, and seeks to streamline oversight of the dental sector by amendment to sections of the general pretreatment regulations.

The AGD policies support the American Dental Association, the ADA, best management practices, including its recommendation for the use of amalgam separators. Moreover, the AGD supports the grandfather clause and the three year allowance for compliance with the new rule, should it be implemented. And we are pleased that the rule does not require existing separators with a remaining useful life to be replaced or retrofitted.

The rule's proposal, that in order to be compliant, practices with existing separators

must continue to have proper operation and maintenance of their existing separators, as well as compliance with best management practices and recordkeeping requirements for ten years after the rule takes effect, makes total sense to the AGD, and as a practitioner who voluntarily put a separator in 11 years ago, I think that is a great rule, and it is still working great, and a nice benefit. However, we are concerned that the real cost of the proposed regulation have not been fully developed, and the mechanism for oversight may need review.

And I will briefly present our concerns in general terms, a far more detailed explanation of our cost-benefit analysis will be provided in writing and we will submit to the EPA before the December 22nd deadline.

So I want to talk about the assumed benefits. It really is important to consider that the amount of mercury that pollutes our surface waters is significantly less than the mercury discharged into the POTWs. By some

estimates only around five percent of the discharge into POTWs from waste dental amalgam actually enters the surface waters in the U.S. as waste treatment plant effluent.

The sedimentation and centrifugation processes used by the POTWs to remove particulates are designed to remove the same types of amalgam particles as amalgam separators. So, while using an amalgam separator will certainly reduce the discharge into the POTWs, its use may not result in an overall reduction of mercury that pollutes our surface waters, since the POTWs will simply continue removing amalgam particles as they are designed to do regardless of that amount.

Finally, the use of amalgam by dental practices is on the decline, as in popularity, and due to popularity and decreasing cost of non-amalgam restorations. I will tell you as a restorative dentist, that train is heading quickly down toward the road where you will not see much amalgam in the future.

At this time I would like to address the cost. The EPA estimates the annual cost for the proposed rule will fall within the 45.5 million to 49.4 million dollar range. This figure is based on EPAs interpretation of a survey conducted by the ADA and the state of Colorado, and it includes a sum of the compliance costs for dental practices as well as the cost of control authorities to administer the new rule.

The Control authorities are primarily the various POTWs. Administration includes the burden on the POTWs to provide the inspections, and yet in further studies and interpretations of data, the ADA has come out with numbers that are far greater, in the range of 380 million to perhaps over a billion dollars to implement all that is provided here, and we would like further clarification on where the numbers really lie.

It is also our understanding that the National Association of Clean Water Agencies has already voiced its concern that the proposed rule may interfere with and burden already successful

local and state programs. As it is, 12 states and 19 localities currently employ their own mandatory amalgam separator programs. Likewise, many POTWs have their own programs to reduce both influent and effluent discharge, and these POTWs may incur significant cost to replace their own systems with system for inspection and enforcement that are compliant with the federal mandate.

So in conclusion, the AGD the ADAs best management practices which include the use of amalgam separators. We are concerned, however, that the EPA may have overestimated the effectiveness of the new rule, and underestimated the cost for its proposed solution. We are also concerned that the solution may have greater actual benefit on paper than in reality, 99 percent is a hard threshold to hit, especially with the technologies we have now. The AGD will provide more detailed analysis of costs and benefits in its written comment to be submitted before the submission deadline.

Thank you again for the opportunity to speak to you on this matter.

MR. STRASSLER: Okay, thank you.

Our next is Ross Fraker.

MR. FRAKER: I'd like to thank you for the opportunity to comment on this recently released set of guidelines and standards for the dental community.

I, by way of introduction, am Dr. Ross M. Fraker a practicing dentist for over 30 years, and I have been having significant interface with the industry, both as a designer, installer, and maintaining equipment for the last 20 years with amalgam separation. I have an engineering background too, so that encumbers me somewhat.

There are basically two types of collection methods utilized with our amalgam separators. One is the catch and hold technique, the other one is, what we would call an immediate processor type of technique. Okay, within each of these categories, there are two subtypes, one in which the amalgam waste portion of the amalgam

separator is opaque, and another one in which the amalgam separator portion is transparent.

Okay, our major concerns are about the opaque containers because a major concern not addressed for all of these opaque models of either processing method, either the catch and hold or the rapid transit (sic). There is no obvious way in the field that the dental office can determine the percent of fullness of the amalgam waste container section, no matter how often it is inspected. I mean, it is a black box. You can inspect it every minute and you cannot tell what is happening.

The dentist will want to comply with the inspection requirements and properly monitor their equipment. All the inspector can report at this time is that the unit is still in place. This means that there is no guarantee that these opaque units are performing at the required proficiency at all, especially when they are full and the owner cannot tell when they are full. This deficiency common to all of the opaque

models must be corrected so that in-house inspections can have a shred of relevance.

A failure by the EPA to recognize this problem and not require adequate fullness percent or indicators for inspections indicates a de facto willingness to allow untreated amalgam waste to pass out of these amalgam waste separator collection units. If you don't recognize the problem, the problem is going to continue to occur. This means that all the hard work that you have done for this document is wasted since it does not really address the real issue, all you have done is required them to possess an amalgam separator unit.

The other concerns we have are with the flow rate limitations used for several of the units to achieve their ISO certification. All of the immediate processor units specified the particular flow rate that their units had to be held to in order to satisfy their proficiency and efficiency requirements. If this flow rate is exceeded, the usual consequence is that the

separator goes into a bypass mode, allowing some of the material to pass out of the separator untreated. This results in a drop in efficiency below that achieved in the certification when the flow rate was properly maintained during the testing. Note, the catch and hold style of amalgam separator does not depend on the flow rate, so there is no problem with that for their ISO testing.

Also note, that the most common time that a relatively high flow rate occurs in a dental office is precisely at the time that the highest concentration of amalgam waste particles is moving into the separator. This is to say that is at the time the office is flushing their suction lines into the vacuum generator. All of the waste material collected during the day is flushed out at the end of the day with several liters, and in some cases, gallons of water. That pushes everything right through and bypass occurs almost all the time. This drop in efficiency can be quite significant because much

of the high amalgam waste particle concentration passes right through. Now, again, a failure to recognize this really negates all of the hard work that you have done before in coming up with this regulation.

Now, here is the solution, based on the two above major concerns, a logical -- it is logical to conclude that to avoid the whole fullness percent dilemma and the efficiency drop off problem, one needs to seek out a catch and hold type and it is transparent, because you avoid both of the visibility and the bypass mode.

We have several other specific concerns and most of these will come to you again in written form. But first of all, I wanted to say that there is no recognition of the style of amalgam separator in which the amalgam waste container or the separator is emptied into an inexpensive recycled container and then repositioned for further use in the amalgam separator. Okay, this -- rather than having to be completely replaced every time. Right now you

require them to be replaced, it is the only word you use, okay?

Secondly, there is a few wordsmithing things, again, these will come to you in written form, much more easy to understand than this quick presentation.

In section 441.40-C-3, you use a word "incorporate," in other words, the amalgam separator must incorporate all of the wastwater, well, in this particular meaning, the word "incorporate" has no meaning. What it should say is that they are required to process at the required 99 percent efficiency, all the waste that comes down.

There is a couple other things to be added, but the final reading of the sentence should read, "it is sized to process at the required 99 percent efficiency, all of the wastwater that comes to it or passes through it in one day," because, you know, you do not want to have just an open ended, "all the water that comes through it."

The other part that I think that can be changed once you require that you have something that someone can actually monitor, either visually or using an analog to know how full their unit is, and also you have some way of preventing bypass mode, is that we can strike out this word "annually" and follow the manufacturer's recommendations. That is in section 441.40 and 441.50 section C-6.

Okay, and again, because of these new ideas in place where you can actually monitor the equipment and you can monitor the flow rate, I think that the inspection time can be reduced from monthly to quarterly, because you are actually having something to report, and then you go ahead and file your reports as you have asked to be done.

Alright, that pretty much concludes what I can present here in this short time, but it gives you the idea that, basically the regulation is good, it is adequate, it works in the field for the dentists, it works in the field for the

people who install it ant maintain it. Most of the time it is the dentists, but there are other equipment people who do that, but I got to see all of it.

I just emptied one of my patient's -- oh, my patients, yeah -- one of my doctor's last week. He had not been maintaining it. It was completely full so we corrected that. I cleaned it out by just emptying it into a recycling container with a little extra water, put it back in place and he is going to be able to use it now, and three years later, because now he knows what to inspect, he will be able to empty it again, this time with a proper amount of sludge and it will continue working. He has had this already for 13 years, so they can last a long time, but, you know, the ten year limit is reasonable a lot of times.

Okay, I think that concludes what I have. I have just a real quick summary to go through, if you have a minute more. It kind of goes over all of these.

In summary, again, I would like to thank you, first of all, for putting all the effort into this, I mean, just reading through that shows that somebody did a lot of work. There may be some contentious areas in your work, but the work is there. I do hope that in the U.S. we can take advantage of this and it can serve as a model for other places, because there are a lot of countries watching what we are doing here, because we have got inquiries already from several different countries. But to have any real impact, as I said again, you have to do more than just ask for the installation of the amalgam separator and let it go at that.

You must recognize and correct the problem of fullness percentage, be able to really understand how they can do that easily, either by seeing it if it is transparent, or having some analog to tell you what percentage this thing is.

Secondly, the flow rate problem as I mentioned, has to be addressed because the flow rate that was prescribed by the media processors

was carefully maintained when they did the amalgam efficiency testing. That does not happen in the field, principally because of the various kinds of staff.

My own staff, I did not even know one of my hygienists puts a quart of water down after every patient. Yeah, all at once, and I tested my model -- or, my units in my dental office the other day. I -- first test was I tested a half a liter of liquid, it went down in four seconds. The second time I did it, I did not keep the tip under the water and it went down in six seconds. I did a whole liter, it took ten seconds. That translates to about a six liters per minute flow rate. It does not come linearly down to the amalgam separator because it kind of lays in the line and all of a sudden you get a splurge coming through, a big bolus of water will come through, you cannot even measure the flow rate, it is just very high.

So, bypass mode is happening every day, and at the time, as I mentioned before, that the

highest concentration of amalgam particles are moving down the line. So, something needs to be done to overcome this difficulty.

And thirdly, I would like to ask you to recognize that the transparent catch and hold style of amalgam separators solve the problem, so there are some of those out there, and it is important to realize that reasonable amalgam waste collection containers make sense, because we do not want to put a lot of extra plastic out in the environment anyway, and it is, you know, less expensive and expenses is certainly one of the big problems. It is less expensive for the dentist not to have to buy a whole new unit every year or even every two years as some companies are. But these units, as I have already demonstrated, can last 15 to 20 years if you replace them properly and still be working properly also.

The idea of self-monitoring is a great way to alleviate the tremendous social cost that we have of trying to have POTWs and the water

districts monitor them, and the fact that they are not doing that. This fellow had been in practice 15 years, nobody had ever come out to inspect his unit; they just do not have the personnel to do it.

In Seattle, they use the public health people to go out and do it and they can do 20 percent a year. Yeah, that is the best they can do. And they do not even know what they are doing, they just look at it and say, "yeah, he's got one." I asked them specifically, that is all they can say, "yes he has one in place."

Finally, there is a lot of -- little bit of wordsmithing here and there, just to add things. That will come in written form.

Alright, thank you very much. I appreciate your time.

MR. STRASSLER: Thank you.

MR. FRAKER: You bet.

MR. STRASSLER: The next speaker is Sylvia Dove

MS. DOVE: I'm Sylvia Dove, representing

Consumers for Dental Choice. Consumers for Dental Choice supports EPAs proposed rule. We believe that this rule is important because amalgam is the largest source of mercury in wastewater. American taxpayers have to pay the price when dentists dump mercury into wastewater and the public wants this rule. Consumers for Dental Choice started a petition calling on EPA to propose this rule several months ago. Already, 13,000 people have signed on so far.

While Consumers for Dental Choice does support the proposed rule, we urge EPA to acknowledge its limitations. First, it does not solve the problem of dental mercury pollution. A separator cannot stop the whole range of mercury releases that occur over the amalgam life cycle. For example, separators do not address dental clinics emitting mercury into the air at high levels, dental mercury from human waste and dental mercury that is cremated or buried along with human bodies.

Second, dentists who do not understand

the amalgam lifecycle might actually increase their use of amalgam because they incorrectly believe that separators are the solution to dental mercury pollution. An increase in mercury would, of course, be bad for the environment.

And third, this proposed rule does not fulfill the requirements of the Minimata Convention on mercury. The convention requires each party to quote, phase down the use of dental amalgam, not just install separators.

So in conclusion, while Consumers for Dental Choice supports EPA's proposed rule, we urge EPA to take further steps to phase down the use of dental amalgam as required by the Minimata Convention, especially, one, tell consumers that amalgam is a mercury product. When EPA administrator Gina McCarthy was in the Connecticut Department of Environmental Protection, they actually came out with a brochure telling dental consumers that amalgam is about 50 percent mercury and mercury-free materials are available and to ask for them. The

US EPA needs to do at least as much as this state environmental agency to raise public awareness about this serious environmental problem.

Two, EPA need to urge dentists to use mercury-free materials. After all, the best environmental practice is not to use mercury in the first place. When former EPA administrator Lisa Jackson was in New Jersey, that is exactly what they wrote into their state separator law. At the very top it tells dentists quote, use mercury-free material when appropriate, and with about 50 percent of US dentist already using mercury-free materials exclusively, it is always appropriate to use mercury-free materials.

And finally, EPA needs to work with other agencies to phase down the use of amalgam, especially in government programs like the Indian Health Service. The US government itself should not be promoting the use of a mercury product at all.

Consumers for Dental Choice looks forward to working with you to address the ongoing

problem of dental mercury pollution.

Thank you.

MR. STRASSLER: Thank you. Next speaker is Al Dube.

MR. DUBE: How are we doing? It is good to see some familiar faces.

My name is Al Dube, I am currently not affiliated with any company or any, sorry --

MR. STRASSLER: Move closer. Yes, thank you.

MR. DUBE: Sorry, thank you.

I am not currently affiliated with any company or any organization, this is me presenting myself as an individual, as a -- someone from the United States. I just want to address a few different issues and somewhat specifically to have tailored to some of the way the document is written, and maybe give you a little of insight on some of the particular -- the particularities of the situation.

In demonstrating compliance one of the questions is, to have the dentists do self-

compliance and self-enroll. I would like to suggest that there be electronic filing, and the reason that I am suggesting this is to use it as an example of what happens in the state of Massachusetts.

Massachusetts has electronic filing. They, on an annual basis -- the dental practices have to self-certify, which is what we have in the current rule. That self-certification then is monitored and at the end of the year, someone from the state then reviews who has monitored and who has not certified, and then they write a letter, and then either do an inspection and or just write a letter of compliance requesting the dental practitioner get in compliance.

It seems to be the most -- simplest at the time -- or at this point, the most simplest and easiest way that we have seen as far as how to keep somebody in compliance, rather than doing continual inspections. Inspections can be taxing on a POTW, especially if you have to do a large proportion of them. I understand from the Napa

situation, if you have a municipality, something like Denver, Denver has roughly five to 600 dentists in it, it would be almost impossible for those to have a regular inspection. So if there was a way to self-certify, that would actually simplify the whole process.

The definition to suggest where an office or a dental office has placed or moved amalgam separators -- there needs to be a little bit more of a clearer definition as to what that actually means. One of the reasons I am suggesting this is that there is a suggestion of emergency. Emergency leads to the opportunity for every amalgam procedure to be defined potentially as an emergency. Requiring an amalgam -- if there was a specific number, let's say on a monthly basis, that if you place a certain number of -- or remove a certain number, whatever that number is defined as, would be more of a clarification, therefore there would be less room for interpretation, as opposed to having something that is more definitive.

Amalgam separators have also been on the market since about 2000, okay? EPA, within this document stipulates and suggests that the life of an amalgam separator is about ten years. With that in mind, if you extend it, the life of an amalgam separator for another ten years, you could potentially have and install the amalgam separator in the field for more than 25 years, which would be more than twice the suggested timeframe for what EPA is suggesting the life of an amalgam separator to be.

So, my suggestion or recommendation would be to look at, instead of saying just ten years from the effective date, potentially go five years from, say, 2010, and then anything after 2010 would be the ten year period. Therefore, you would be at least minimizing by at least five to ten years, the extent of how long an amalgam separator may be in place.

EPA is also suggesting in this document that the potential of the dental office self-certifying itself, inspecting on at least on a monthly

basis, as a previous speaker has suggested, amalgam separators have been known to clog, have been known to overflow, have been known to have potential issues with them that need to be monitored in somewhat of a regular basis. I do not find once a month too arbitrary or too invasive. It does not have to be inspected specifically by a dental professional, it could be inspected by anybody in the office, but it should be catalogued and that catalogue probably be submitted as a part of the annual report, as suggested or recommended by the current proposed rule.

I am also recommending as -- again as a previous speaker suggested, the opportunity for the amalgam separators to be clear and or transparent. There is an assumption based on the way that the current rule is written that there would be an opportunity for visual indication, or some way of digitally understanding whether the functionality of the system is actually operating or not in the field, and that is the most

critical aspect of it.

Even from the POTW's standpoint, if there is a cause for an inspection, if a dental or the POTW does an inspection and then walks in, if the system is considered to be what we call a black box system, where you have no way of looking inside the system at all, there would be no way onsite to determine the functionality, whether it was working, whether it was in bypass, or otherwise. Most current systems right now, there is probably about half the systems that are currently on the market right now have either a clear or some transparency to them, so it is not an unusual circumstance for these things to be made. So, I would also suggest that other companies would have the opportunity and availability to do so as well.

Along with that, there is a, the ISO standard and the ISO -- current recommendation for the ISO standard. The ISO standard is actually a two-tiered standard, it is not only about efficiency. There are specific

requirements that are required for amalgam separators. If -- there are of different types, so they are a type one, two, three, and four types of amalgam separators. The first one is a sediment -- sorry, a centrifuge, the second one is sedimentation, the third one is filtration, and then the fourth one is a combination of any of one, two, or three.

There is an exception for type two amalgam separators if they have a clear visual indicator, in order for them to proceed without an alarm system, however, type one, three, and four are required to have alarms. Currently, right now, and including testing facilities here in the United States and overseas, do not recognize the fact that there have to be electronic alarms on some of these systems, and they are passing certifications without alarm content. Okay?

So, if you look at the way the regulation is currently written, there is no mention of any of the physical attributes that the ISO

certification has, it is clearly only directed at efficiency. This is not an unusual circumstance. If you look at the regulations that have been passed in most of the states, they also have ignored it from the way that the statute has been written.

My suggestion or recommendation would be, either, if you want to use the ISO standard, use all of it, or at least acknowledge the fact that that does not have to be abided by.

One small little comment, you have the state of Louisiana as one of your 12 states regarding the fact that they have a statewide mandate, they do not. Minnesota, however, does, and they are not mentioned, so you might want to just make a note of that. They do have a local mandate in Louisiana, but it is not a statewide mandate currently.

Another component to look at, when dealing with best management practices, and it is something that kind of slips by, the current regulation or rule discusses any material that

would be -- come in contact with particulate amalgam to have to run through the amalgam separator. What is missing within this, is the cuspidors, or the spit sinks -- what is defined as a spit sink by some folks.

Cuspidors are typically gravity-fed, which means they do not go into the vacuum system, which means they would not ever be processed by an amalgam separator, if that is the case. There are adaptors that are available through the local dental supply companies, so it is possible to do this.

The requirement was put into place in Montreal, it was also put into place in Providence, Rhode Island, or the Narragansett Bay Commission, when they did their program. So, it is something that is possible. It is something that is readily available to the dental community right now.

In, 14, talking about the proposed regulations, there is a repeated number that suggests within the ISO standard, that we are

talking about total mercury. We are not talking about total mercury when we talk about or have a discussion about amalgam separators, we are talking about particulate. So just for clarification purposes, amalgam separators do not address any dissolved mercury or anything else, it is -- they are only there to be designed for particulate. So I would make a strong recommendation that that be changed to total amalgam particulate standard, or total amalgam particulate removal.

I would also suggest in the general definition, and again, mostly for clarity purposes, when you -- when I have had discussions with a lot of the POTWs and gone to a lot of the pretreatment programs, one of the clearest things that comes out from the POTWs themselves when discussing regulations and rules, is more specificity. Something that is more defined so there is less room for interpretation.

With regard to the general definition of an amalgam separator, if you just discuss it as

an amalgam separator that collects particles, it again, and you refer to the ISO standard, it opens up for particulate parts of determination and potentially interpretation for certain things, specifically going towards this clearer, transparent type of scenario, if you would add that portion into the descriptive part of an amalgam separator, it then is more clearly defined and there is less room, again, for interpretation for what you may or may not want.

In section 441.40, the discussion of the requirement for a three year extension after the implementation, actual implementation of the dental rule in and of itself, amalgam separators have been known and been discussed in the dental industry at a minimum since 2007 when the American Dental Association added it to its best management practices. Prior to that, they have had at least two, if not three articles published in the American Dental Journal. So this, from a dental standpoint, an amalgam separation is not a new topic, it is not a new understanding or idea.

I have been to multiple different pretreatment programs around the country. I have been to Napa, I have also been to region -- much of the different regions. This is a program and this is something that has been discussed over and over and over again. As a matter of fact, it has been discussed to the point where people are almost frustrated with the fact that this rule has not come out.

There is a clear understanding of what needs to be done, or at least to get the program started, and that starts now, it should not start at the effective date of the rule, so they can -- there is room and time right now for a proposed opportunity to start looking into what you need or don't need to do.

The recommendation I am suggesting is to take one year off of that to 24 months. The other reason for that, is based on sales data, previous sales data from a company I used to work for, it is clearly defined that the vast majority of the amalgam separators that get installed, get

installed within the last six months of the impending rule. That has happened in state, after state, after state, after state. So, the extension of the time would not necessarily add value back into having separators put in place more often, as far as what we have seen in the past.

Now, what I can also tell you, is that the dental community, at least from the distribution side, and the sales side of things, we will be talking about this rule extensively. They have already heard that it is coming so there will be a lot of information that is going to be coming off to the dental community, not only from their ADA, not only from their state regulatory agencies, not only from the POTWs, but also the people that visit their office on a regular basis to provide products and services for them. So, this will be something that will be coming up multiple times. There will be a lot of education on this process and its programming.

I just want to see if there is anything

else. Oh, I have already covered the rest of this.

I will be submitting formal comments. I am not going to submit them now, I will be submitting formal comments with the rest of the additional things that I will also be adding into here. I would expect that you will be getting many, many, many, many comments to this rule.

It has been a contentious issue for quite some time now, and EPA, I mean, I believe the first time we were supposed to have a rule, it was supposed to be November first of 2011, so we are already three years in arrears from when the original projection of this conversation should have been started, or at least the projected time of it being started.

So, I would implore that as -- not so much as quickly as possible, but as efficiently as possible, you do your due diligence as you have been doing, and I look forward to seeing what the final rule is.

Thank you.

MR. STRASSLER: Okay, Sally Cram

MR. WOOD: While you are coming up, just judging from the looks on a few people's faces, if I was reading that correctly, were folks having a hard time hearing?

Okay, I think step one might to just get that microphone as close to you as you can. The other one is not for amplification I do not think that is the sound system.

MR. STRASSLER: That is right.

MR. WOOD: So, the small microphone on the podium, that is the one that is amplifying your voice, so let's try this for a minute or so, and one option may be, I don't know if we can put another microphone up there.

MR. STRASSLER: We may be able to adjust the sound levels.

MR. WOOD: Okay, so we are going to work on it.

MR. STRASSLER: Let's see how that goes. Okay, thank you.

COURT REPORTER: If you speak up, that

would help too.

MS. CRAM: Good afternoon, my name is Doctor Sally Cram, and I am a practicing periodontist here in Washington, D.C. Today, I am speaking on behalf of the American Dental Association, the largest dental professional association in the United States, which represents over 157,000 dentists including over 65 percent of active U.S. dentists.

The ADA greatly appreciates the opportunity to provide our preliminary oral comments on the EPA's proposed rule for the dental category. Most dentists use services of their local sewage treatment systems or publicly owned treatment works, POTWs. The issuance of a pretreatment rule governing the discharge from dental offices would directly and significantly impact tens of thousands dentists and their patients.

These comments I am making today are only preliminary, we are still studying this proposal in detail. The ADA supports the use of amalgam

separators and includes them in its best management practice guidance for dental offices. Specifically, our BMPs include the use of separators that comply with the international standards organization standard.

In 2010, the ADA governing body, the house of delegates unanimously passed a resolution supporting the promulgation of a pretreatment rule governing applicable dental offices as long as the final rule complies with nine common sense principles, including the use of amalgam separators that comply with the ISO standard.

The ADA reaffirms its support of a pretreatment rule that requires amalgam separators consistent with these nine principles. The proposed rule complies with most of these principles and we applaud the EPA's efforts to incorporate them into this rule. Unfortunately, the proposed rule, in its current form, fails to meet some of these principles. Our final, more detailed comments will explain

these problems, and offer constructive solutions that will allow the EPA to use a final rule that is effective and workable, and one that the ADA can support.

The ADA's review is ongoing, but our preliminary review had identified three major concerns which the agency must address before the ADA can support the EPA proposal.

First, the ADA and National Association of Clean Water Agencies have stated that the rule should not impose undue and unnecessary burdens on either dentists or municipalities that operate sewage treatment plants. The ADA believes that some of the implementation requirements create unnecessary burdens with no discernable environmental benefit.

For example, the rule requires inspection of separators on a schedule unrelated to their recommendations of the separator manufacturers. The ADA's final comments will describe these burdens and offer alternative approaches that ensure that the regulators, whether the POTWs

themselves, state governments, or the EPA have the assurance that amalgam separators are operated effectively.

Second, in addition to requiring installation of amalgam separators that comply with the ISO standard, the proposal actually establishes a 99 percent removal efficiency requirement for total mercury. These provisions are inconsistent.

First, the ISO standard is validated at 95 percent and is not a validated test for measuring a capture efficiency of 99 percent.

Second, EPA's proposed removal efficiency is based on removal of total mercury, not particulates. This requirement deviates from international community requirements as incorporated into the ISO standard. By citing conflicting requirements, EPA's proposed rule is not workable.

Third, EPA's proposal is based on incorrect numbers and assumptions. For example, the EPA utilizes a 1982 POTW study of total

mercury reductions in POTW effluent to justify its assumption of a 90 percent amalgam particle removal efficiency for the POTWs. This is not scientifically supportable and underestimates the amount of amalgam particulates that the POTWs collect. In our written comments, the ADA will document the changes needed to assure a scientifically sound rule.

The ADA believes that the EPA's proposed rule can be modified to comply with the ADA's nine common sense principles while still accomplishing the goal shared by us all, to protect our environment.

Thank you again for allowing me to share with you our preliminary thoughts.

MR. STRASSLER: Thank you. Next is William Purves.

MR. PURVES: Thank you very much for allowing me to speak today.

What I am going to be discussing though, is a little different in terms of the amalgam separators. My business is that I have been

analyzing amalgam separators and their efficiency since 2000 -- or, I'm sorry -- yeah, since 2003. I was contracted by a couple of PTOWs (sic) to examine their issues with regards to mercury entering their systems. So, as a result of that study, I then continued to do an additional study. The data that I have accumulated over this period of time is quite disturbing in that most of the amalgam separators are -- even though they may have a 99 percent efficiency, the reality is, that additional one percent is a tremendous amount of mercury that enters the PTOW (sic).

In terms of numbers, it would probably be difficult to discuss here, but we are talking billions of parts per trillion, because that is what we deal with in mercury at a PTOW (sic). The PTOWs (sic) in the United States have a 12 part per trillion limit, unless they are in in the Great Lakes, which is a 1.3 part per trillion limit. These numbers, based on the data that I have already sent to Mr. Highsmith would, in fact

-- the separators are creating more of a problem when it comes to dissolved mercury, not particulate.

One of the things that has never been examined, in terms of mercury separator -- amalgam separators is the fact that dissolved mercury is created by the separator. It is because of the way mercury can, in fact, dissolve in water, and I have data that we have generated over and over again that shows the rate at which mercury dissolves in water and then enters the water waste stream.

The other thing is, is most of the PTOWs (sic) are not able to take a sample from the dental office separator itself. Where they take their samples at are usually in the street at a manhole. When they take the sample at that particular location, what happens is, is there is usually a significant amount of dilution.

The other issue is, is that depending on the type of vacuum system the dental office uses, also has a dilution -- can have a dilution

effect. For example, if a dental office uses what is known as a wet vacuum, that water is mixed with the discharge from the amalgam separator and thus, dilutes the amount of mercury that is potentially entering the system. However, we have done -- we have accumulated data from many offices out at the manhole, at the -- and a couple of my PTOWs (sic) that we do work for are having significant issues with some of the discharges, in that when they have a high discharge from the dental office, they are not able to meet their discharge at the plant, because the dissolved mercury, unlike particulate, goes through the plant. It does not get captured at the plant. That is where the problem lies.

So, in addressing this whole thing, we did a number of -- we were lucky enough to have several dentist allow us to come into their office and actually examine their separators, take samples from their separators at the discharge point, and I generated a significant

amount of data regarding that. In addition to that, we have also done additional study on the amalgam itself, the rate at which mercury is released in water as dissolved mercury.

So, when it comes to this particular -- when it comes to this issue, dissolved mercury is just as much an issue as the particulate, and that 95 percent efficiency -- if 99 percent is not enough, 95 percent is not even close.

The other issue is, is we have actually looked at several amalgam separators themselves and the way they operate, and have noted that many of these separators are inefficient in terms of the release of mercury into the environment, especially dissolved mercury. There is, or there are currently one, and maybe two separator companies that are now looking at modifying their units to use what we would call treatment, in terms of removing the dissolved mercury as well as the total solid mercury.

We have already done a preliminary test on one unit and just with a very simple

modification that costa approximately 45 dollars in total cost, we were able to reduce the amount of mercury discharge down to under 5,000 parts per trillion, which, if we were to put that in percentages, it is very, very, low.

So, our issue here is, is that we are -- the -- we are not addressing dissolved mercury. Dissolved mercury is -- in this case, is in some cases with some of our PTOWs (sic) is a major issue. We have a couple of PTOWs (sic) that have been able to identify the dental office literally that is causing their problem, and the separator is not -- the other problem is, because of maintenance and separator design, they are not capable of completely resolving the issue.

So, more has to be done in terms of examining what is actually discharging from the separator itself, and in terms of design of the separators, the separators themselves may work well in terms of removing solid particles, but they also generate a lot of dissolved mercury, and that is really the issue that occurs here

more so than the particulate. The particulate can be removed down at the wastewater treatment plant, but the dissolved mercury does, in fact, go through there.

And I have a second -- another study that we did in terms of looking at the concentration of dissolved mercury entering the plant from various sources and what effect it had on the discharge of the plant itself. This particular plant we looked at has a six million gallon per day discharge on average, which is a lot of mercury -- a lot of water, and in some cases the dental office can contribute as much as ten parts per trillion in that discharge, even at six million gallons per day. So, it becomes a real issue in terms of the way the systems are built, the way the dentists are inspecting them, or even inspection itself. There are some companies that are, in fact, looking at making changes in design to handle this particular issue, but right now, it is an issue that needs to be addressed in the future on this whole process.

Thank you.

MR. STRASSLER: Could you state your name and organization?

MR. PURVES: Oh, I'm sorry, Bill Purves and it is Purves Environmental.

MR. STRASSLER: Very good. Thank you.

MR. PURVES: Thanks.

MR. STRASSLER: Next is Berta Yurkovsky.

MS. YURKOVSKY: Hello. My name is Berta Yurkovsky, I represent Medentex. We are a manufacturer of -- louder?

Is that better?

MR. STRASSLER: Get closer to the mic.

MS. YURKOVSKY: Is that better?

MR. STRASSLER: Okay, great.

My name is Berta Yurkovsky, I work for Medentex. We are a manufacturer of amalgam separators -- a particular amalgam separator, and we are also a recycler of amalgam-containing wastes. We have actually been around for 30 years in Europe as the largest -- one of the largest companies in the industry. And, I

appreciate the opportunity to come and talk to -- about the proposed mandate.

Is this okay now?

MR. STRASSLER: Yean, stay close to the mic.

MR. YURKOVSKY: Okay.

So, a few things I wanted to address about the proposed mandated is in regards to the ISO 1143 certification for amalgam separators, which does state that either the amalgam separators need to be -- need to have a full level indicator, or have a manufacturer-scheduled replacement.

Now, full level indicators do have the potential to not be exactly accurate because of splatter and just, splatter building up on the outside of the walls. And, this also relies on the dental offices to make sure to go and check the amalgam separator frequently, which is not always going to happen, in -- realistically.

Another type of process based on the ISO 1143 standard is that the manufacturer has a

scheduled replacement in place where they contact the office and let them know when they need to be replaced. There is different units that are fitting for different sized offices and different configurations in the office. So, I feel like that is a better system to go by.

I also do not know that a bypass is necessarily the right way to go about it, to allow a bypass to be in place. The ISO 1143 actually does not allow for a bypass, which is an international standard. So, that should not be included in the mandate, or in the proposed rule.

I also feel that a completely closed system should be placed in the mandate that the dentist and his staff and the technicians that are dealing with the amalgam separator are not becoming exposed to the contents within it. So, I think that should be included somewhere in the mandate.

One of the points in the proposed rule was that the EPA would have to keep track of which dentists are being compliant with the

proposed rule -- or with the mandate once it is released. One of the ways that this -- we could go about this is that the manufacturer keep the records, or the recycling company keep the records of which offices have a system in place and how often it is being replaced, based on when it is being turned in, and if they have them on a schedule of replacement, they will be able to see those records and give that information to the EPA if required.

There was also a -- it was mentioned but I think it needs to be more clear in the proposed rule, that a waste container somewhere in the office needs to be required with the rule for any chairside traps, solids collectors, cuspidors, that also do come into contact with amalgam but do not necessarily go into the amalgam separator. Other areas of waste contamination that could occur, especially for waste management companies that handle other types of waste, like sharps and biohazardous wastes, they -- a lot of times do come in contact with amalgam-containing waste and

then they have a spike in their mercury emissions and that could be avoided by having an amalgam waste container somewhere in the office.

I think it should also be made clear in the proposed rule that the system needs to be replaced based on manufacturer specifications, because there are different units in place and different sorts of technology. A lot of different amalgam separators have a maximum storage of one year to keep the lines clean, which I think should also be included in the mandate, for safety purposes, so that there is no buildup of bacteria or anything of the sort. And if it is -- a lot of states that have mandates for a state level do require that it be stored up to one full year.

Another thing that should be made clear in the proposed rule is, line cleaner and disinfectants that contain bleach or non-neutral pHs should not be allowed with the system because it could lead to the breakup -- I think that should be made very clear that that is, kind of -

- nullifies the system and how it works.

Finally, I think another point that should be made is that there are different configurations and setup for different size vacuum -- I'm sorry, different vacuums, wet vacuum systems versus dry vacuum systems in different sized offices, based on dental staff. So, they should accommodate their office based on that information -- based on their size and their type of vacuum system.

I appreciate the opportunity to present my views on the proposed rule, and I am eager to see it come to fruition.

Thank you.

MR. STRASSLER: Okay, thank you.

Those are all of the speakers that have signed up to testify.

Is there anybody else who wishes to testify?

[NO RESPONSE]

Okay. Well, thank you. All of the testimony will be in the record. The record will

be available on the regulations.gov website. We will also have a transcript in the record at our website shortly, and the comment period for the proposed rule is open. Currently the comment deadline is December 22nd, but as Rob mentioned earlier, we are considering an extension to the deadline. You can submit comments in writing or electronically. The procedures for that are in the Federal Register notice. Please see that for instruction on how to comment.

Someone has a question.

Sir?

MR. FRAKER: You have two types of comments --

MR. STRASSLER: It might be better if you stepped up --

MR. FRAKER: Thank you. I do not have my copy of the Federal Register now, but there are two types of comments requested. One of them, you wanted to have received by the 22nd of November. I could not understand exactly what that category of comment was. We have the

Federal Register here, I can look it up in a couple of minutes and get back to you.

MR. STRASSLER: So, the question had to do with the two different deadlines for the comment period --

MR. FRAKER: Right.

MR. STRASSLER: Associated with the rule. The first is a 30 day comment period and that is on the ICR, the information collection request that is submitted to OMB as part of the proposed rule.

MR. FRAKER: I am sorry, I have a cold, I can --

MR. HIGHSMITH: It is reporting requirements that are in the rule.

MR. FRAKER: Yes.

MR. STRASSLER: So these are the recording requirements that would be put in place by the proposed rule, and the comment period for that specific document is 30 days.

MS. MATUSZKO: It is actually more specific than that.

One of the things we have to do when we propose a rule is to estimate the burden associated with requiring --

MR. FRAKER: Are you talking about --

MS. MATUSZKO: The reporting requirement. So, it is the, you know, self-certification, it is for the POTW to view the self-certification, and so we came up with estimates for that. They are in the rule, they are in the ICR supporting statement. So, if you think we did them right, or we did them wrong, that is the comments that have the shorter comment period. Everything else has the later comment period.

MR. FRAKER: Alright, thank you.

MR. STRASSLER: And the later comment period may be extended. We are considering that extension now. So, if we do extend the comment period, we will announce that with a federal register notice, and it will also be up on our website. So, basically any new information, you can look on the website for that.

So, that concludes today's hearing.

Thank you for coming.

[Whereupon the hearing concluded at 2:05 p.m.]