Appendix B: Written Comments Submitted by Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix B1. Written Comments from potential SERs following the March 17, 2016 Pre-Panel outreach meeting

After the March 17, 2016 pre-Panel outreach meeting, potential SERs submitted two sets of written comments, which are provided in this Appendix:

1. Globe Engineering Co., Inc. from Wichita, KS
2. Nobert Plating Co., Rob Sickles, from Chicago, IL

1. Globe Engineering Co., Inc. from Wichita, KS

Globe Engineering Co., Inc

1539 S. St. Paul; Wichita, KS 67213

TSCA Section 6 Proposed Rule: TCE in Vapor Degreasing

Pre-Panel Outreach Potential SER Questions for Discussion

These are informal questions that aim to guide discussion on your work practices and your experiences with this chemical. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives.

If you are interested in providing this or other information in writing, please see the contact information at the end.

For all vapor degreasers:

1) Your business:
    a. What items do you degrease with vapor degreasing? Sheet metal, tubing, screen (all parts are for Aerospace Industry)
    b. What type of system do you use (open-top, closed vacuum, etc)? open top
    c. What size system do you use? 165 gallon capacity tank , 288 cubic feet
    d. How significant is vapor degreasing to your business overall? An integral part of our operations. Most of the parts we manufacture go through at least once, if not multiple times.
    e. Do any particular items or soils present special challenges? Larger items, long tubing, forming oil
2) Current work practices related to vapor degreasing:
    a. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity? Unknown
    b. Do the types of vapor degreasers we are considering (open-top, enclosed vacuum, continuous strip, and inline belt vapor degreasers) seem representative of those currently in use for small businesses? Unknown, our tank is open top
    c. How many hours per day do you operate your vapor degreaser? 10 hrs./day. How many days per year? 250 days/year. Is there any difference for the different types of vapor degreasers? Only have experience with our open top degreaser
    d. Regarding the operation of various degreasing systems in small businesses, do you think the following is a reasonable range of solvent use?
        i. Between 452 and 1,120 gallons of TCE per year for all open-top vapor degreasing units? Would have to say no, our current use is 1300-1600 gallons a year
        ii. Average annual use of 1,500-1,600 gallons per year for conveyorized vapor degreasing units? Unknown
        iii. Average annual use of 400-500 gallons per year for enclosed vacuum vapor degreasing units? Unknown

e. When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc)? March 2014. Installed a new steam valve that auto-modulates the control of the vapor and steam level. Installed for better control and allows the safeties to work in conjunction with tank so that if we have any sort of problem the safeties shut down the steam valve and the tank. What prompted this update? To provide easier and better control for the vapor level.
f. How large is your facility that uses vapor degreaser? (ie., dimensions of the room that the degreaser units is used and overall size of facility) Room is 17' x 18' (306 sq. ft.) Main facility building is 480' x 148' (71,040 sq. ft.)
g. How many employees perform degreasing operations? 4 How frequently? Daily (M – F)
h. How many employees are located in the same room with the degreaser unit but not necessarily operating the machine? 2
i. What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)? Client preference, Impact on item (cleanliness) and safety

3) Using TCE in your business:
   a. If TCE were not available for degreasing, how would you adjust and what would the impacts be on your business? Customer Approvals, Research, Shut us down until alternative solution found
   b. What are your current and best practices to protect workers from exposure to TCE? For example, do you or your colleagues use ventilation or engineering controls, personal protective equipment, worker training, or other methods? Regulations, cooling coils limit emissions, fresh air ventilation, updated controls, Daily, Weekly, and Monthly monitoring, lid to close when not in use, required training.
   c. What are the benefits to your business of TCE? Customer approved quality and requirement.

4) Exposure reduction for vapor degreasing
   a. What are your experiences with:
      i. Installing or updating ventilation and local exhaust? Minimal, Added monitoring
      ii. Installing or operating other engineering controls? Good, 2014
      iii. Equipment changes to reduce exposures? Rack Editing (round bar racks, reducing entrapment and transport)
      iv. Monitoring worker exposures to chemicals in the air? Conditions have been tested in the past
      v. Air-supplied respirators? Not in daily use, they are used for periodic cleaning in confined space of the tank
      vi. Other personal protective equipment? N/A
   b. If you have changed or updated your exposure reduction technology or methods, how long did that process take? Minimal timeframe, we have taken action to keep lid closed whenever tank not in use.
   c. What do you do to comply with OSHA standards for TCE? Monitoring and usage logs

5) Substitutes and alternatives:
   a. How do you know which chemicals are in the products you are using? SDS
   b. What are the trusted sources of information for you about chemicals you use? Osha, ERG, and NIOSH

c. Have you tried using alternative chemicals or methods for degreasing? What were the results? N/A, TCE is a required solvent, obligated for use by customer specs
   i. Please discuss alternative methods to vapor degreasing as well as alternative solvents or equipment in your vapor degreasing process
   ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation? No
   iii. If you have tried or switched to alternative chemicals or methods, how long did that process take? Did it require equipment modifications or new equipment purchases? N/A

d. If TCE could no longer be used for vapor degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? Unkown For example, are there particular alternatives that are more suitable for small businesses? Unknown

6) Regulatory options
   a. Which of the regulatory options presented today would you recommend? Need new industry standard to be able to get away from TCE
   b. Cost estimates: In your experience, are the cost estimates reasonably representative for both options presented? Unknown at this time
   c. Can you think of ways to add flexibility to this rulemaking for your small businesses? A defined time frame to gather information and testing of new solvents (what we use is not really up to us, customer driven)
   d. How do you learn about EPA regulations and what you should do to comply? OSHA, Direct from EPA
   e. What is the best way to reach out to members of your industry? Customer Relations

Contact information:

7) Nathaniel Jutras, RFA/SBREFA staff contact
EPA Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov

2. Nobert Plating Co., Rob Sickles, from Chicago, IL

From: Rob Sickles [mailto:rsickles@npc1903.com]
Sent: Thursday, March 31, 2016 2:47 PM
To: Jutras, Nathaniel <Jutras.Nathaniel@epa.gov>
Subject: RE: TCE SBAR Pre-Panel Follow-Up

Hello Nathaniel,

My main comment is:

We currently run an newer open top Degreaser that is set up to run "EnSolv" brand n-propyl bromide the solvent capacity is 71 Gallons.

We made this switch about three years ago due to health concerns associated with Tri-Chlor. My one concern here is that we made this switch and are now finding out that this may not be the option we had thought it was from the beginning. If this is being presented as an/the alternative it should be noted that this most likely will not be a long term solution and may end up soon where TCE is now. An effort should be made to vet some real and viable alternatives that give the end users, such as airplane/aerospace manufacturers, government defense contractors, weapons designers, Medical equipment manufacturers etc.....

I also sit on our local Metal finishing association board and could bring this to their attention for further comment. There was not enough time to accomplish this for this round.

Thanks for your consideration.

Best Regards,

Rob Sickles, C.E.F.
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Appendix B: Written Comments Submitted by Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix B2. Written Comments from SERs following the June 15, 2016 Panel outreach meeting

After the June 15, 2016 meeting, the following SER submitted eleven sets of written comments, which are provided in this Appendix:

1. Globe Engineering Co., Inc., Jeff Teague, President and Scott Lauderbaugh, EHS Coordinator, from Wichita, KS
2. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/22/2016 comments)
3. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/28/2016 comments)
4. Marquette Tool & Die Co., Gerry Richardson, from St. Louis, MO
5. McMillan Electric Company, Floyd Ankrum, Plant Engineering Manager, from Woodville, WI
6. Nobert Plating Co., Rob Sickles, C.E.F., from Chicago, IL
7. Parts Cleaning Technologies, David Crandell, President, from Redford, MI
8. Precision Machined Products Association, Miles Free, Director, Industry Research and Technology, from Brecksville, OH
9. E. C. Styberg Engineering Company, from Racine, WI
10. Viking Drill and Tool, Inc., from St. Paul, MN
11. Whittet-Higgins Company, Andrew A.O. Brown, from Central Falls, RI

1. Globe Engineering Co., Inc., Jeff Teague, President and Scott Lauderbaugh, EHS Coordinator, from Wichita, KS

Globe Engineering Company, Inc.

July 1, 2016

Ref: SER input regarding TCE Usage in Vapor Degreasing operations

Globe Engineering is a company that manufactures assemblies and parts that are utilized in the aerospace industry. These assemblies and parts are manufactured from metal components that include sheet, plate, bar, and tubing raw material. We currently employ 212 people. The operation of our Vapor degreaser with the use of TCE is an integral part of the cleaning operation for most of the parts and assemblies we manufacture. This is due to the configuration and form of the sheet metal parts, in addition to the small diameter tubing that is bent for the various systems of an aircraft.

There are 2 – 4 employees that directly operate the Vapor degreaser. And an additional 2 – 4 employees that are near the system to support the degrease operations. The Vapor degrease machine is in operation 10hrs/day Monday – Thursday; 9hrs/day on Friday; and also for 6hrs/day on Saturday. Our degrease machine is located in a separate room at our facility. The operators are in this room when they are loading or unloading a rack from the machine, or if they are rinsing parts. While the parts soak, the operators go out of the room to rack and un-rack the parts for delivery to the next shop.

The Vapor degrease machine was designed and built by Globe Engineering and has been in operation for 30+ years. It is an open top machine with a cover. The opening is 7.50ft x 3ft. There is about 165 gallons of TCE in the tank while the machine is in use. Our current use of TCE is 1300-1500 gallons a year. There have been upgrades and modifications made to the controls and work practices of the machine. Most recently, we have added 2 layers of refrigeration coils to the freeboard refrigeration device. We rebuilt the exhaust system to include 2 separate exhausts, an upper and a lower. We installed a new steam valve that auto-modulates the control of the vapor and steam level.

All degrease operators are provided training and must be certified before they can operate the degrease machine. This involves classroom training on the proper use and associated hazards while performing degrease operations. It also includes a practical test that all operators must pass to receive certification. We also protect exposure through the use of engineering controls and standard operating procedures. The hoist speeds, dwell time, freeboard temperatures, and room parameters are monitored and documented. There is also a local exhaust ventilation system to reduce exposure in the area. General standard operating procedures are employed to reduce the consumption and exposure risk as well.

Periodic testing is performed to monitor exposure levels. The testing is performed by an outside vendor. The exposure levels are determined through the use of a personal sample pump equipped with charcoal tubes. The monitoring equipment is provided by the vendor. At the completion of the monitoring session, the data is read by the vendor and a report is supplied to Globe Engineering. The most recent monitoring session provided data to show that the exposure levels remain below the OSHA requirements. The employee was sampled for a full shift and a second sample was collected for 15 minutes as the employee actively lowered and retrieved parts from the tank. The full shift sample result was 39.8 ppm. The 15min sample was 153ppm.

Our Vapor degrease operation is utilized in accordance to the various process specifications that are authored by the OEM's within the aviation industry. Any substitute or alternative method used to achieve the cleaning required would have to ensure that it meets these various specifications. It has been determined that it would not be economically feasible to replace the existing machine due to the initial cost of machine, not having the required floor space available, and the reduced cycle time from current that would be experienced with an enclosed machine.

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2. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/22/2016 comments)

Kearflex Engineering
66 Cypress Street
Warwick, RI 02888
Brian Peskin, VP 6/22/2016

TSCA Section 6 Proposed Rule: TCE in Vapor Degreasing
Panel Outreach SER Questions for Discussion
6/15/2016 Meeting 10:00 - 12:30

For all vapor degreasers:

1) Your business:

a. What items do you degrease with vapor degreasing?

Small formed parts, machined parts, precision assemblies.

b. What type of system do you use (open-top, closed, closed with vacuum, etc)? Can you provide a brief description of your system and how it works?

The system has a sliding top that is closed during degreasing and when not in use. The top slides open and a small crane slowly lowers the parts in a basket into the degreaser and closes the door. After timed submersion in the degreasing fluid, the crane lifts the parts into a cold drying zone within the machine for a "dwell" period. Once allowed to dry, the top is opened and the parts are lifted out. The operator is not touching liquid TCE - the parts are dry upon removal. Vapor is condensed and kept within the machine. The operators are usually not present during the timed cleaning cycle.

Although classified as "open top" the machine has a sliding cover and a cold vapor barrier to contain vapors.

c. What size system do you use?

Our system holds about 5 gallons of TCE.

d. How significant is vapor degreasing to your business overall?

Virtually every part we manufacture must be cleaned is the degreaser.

e. Do any particular items or soils present special challenges?

Machining and lubrication oils.

2) Current work practices related to vapor degreasing:

a. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?

Our 5 gallon machine is common for small businesses like us.

b. Do the types of vapor degreasers we are considering (open-top, enclosed vacuum, continuous strip, and inline belt vapor degreasers) seem representative of those currently in use for small businesses?

For small capacity, the open top machine is believed to be most common.

c. How many hours per day do you operate your vapor degreaser? How many days per year? Is there any difference for the different types of vapor degreasers?

For our business the machine operates 8 hours a day for 50 weeks per year. This is standby operation. The machine is used for cleaning an average of 3 hours per day. As the process is timed and semi-automatic, operator presence at the machine location is an average of 30 minutes per day. The machine can run 4 to 6 cleaning cycles per hour and only requires a few minutes to load and unload.

d. Regarding the operation of various degreasing systems in small businesses, do you think the following is a reasonable range of solvent use?

i. Between 452 and 1,120 gallons of TCE per year for all open-top vapor degreasing units

We can easily meet this limit with current operations.

ii. Average annual use of 1,500-1,600 gallons per year for conveyorized vapor degreasing units
iii. Average annual use of 400-500 gallons per year for enclosed vacuum vapor degreasing units

e. When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc)? What prompted this update?

The last update was 6/2008. We purchased a new and compliant vapor degreasing machine. Procedures were established, and training and operator certification was performed. There are weekly and monthly operational tests performed and recorded to ensure the unit is functioning correctly.

f. How large is your facility that uses vapor degreaser? (ie., dimensions of the room that the degreaser units is used and overall size of facility)

Degreaser room 1,700 sq ft / Building 12,500 sq ft.

g. How many employees perform degreasing operations? How frequently?

About 12 employees operate the degreaser at random depending on activity with no more than 2 hours in the vicinity of the machine per day total. Most of the use would be by 5 employees with no more than 2 hours for any one person.

h. How many employees are located in the same room with the degreaser unit but not necessarily operating the machine?

0 - 5 Employees in the room. Most common full time occupancy is 2.

i. What are the most important factors in degreesing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?

Our products are highly engineered and have specific manufacturing controls on them once approved by our customers. Designs are tested and approved, and no process changes are allowed without review for potential results that would be different from the originally qualified product. Our parts must be clean, free of oils, and free of moisture. One of the greatest potential issues with aqueous cleaning is water residual, and the potential for corrosion conditions from water to be introduced in an undetectable manner.

3) Using TCE in your business:

SBAR Panel Discussion Questions: TCE in Vapor Degreasing

a. If TCE were not available for degreasing, how would you adjust and what would the impacts be on your business?

In the short term, we would be shut down. Our customers include aerospace, general aviation, military aviation, medical, and other critical markets. Changes to long proven products are not permitted. Kearflex is a critical sole source supplier to several airframe platforms and the impact of a sudden loss of TCE would be catastrophic. Bypassing the procedures for changing a cleaning process could be a threat to safety, and would not be allowed. TCE had been integral to our processes for 40+ years.

b. What are your current and best practices to protect workers from exposure to TCE? For example, do you or your colleagues use ventilation or engineering controls, personal protective equipment, worker training, or other methods?

The area is well ventilated. Personnel exposure is limited to 2 hours per day direct contact with the degreaser. Operators are trained and approved for using the degreaser. Gloves and masks are available for handling and transferring the TCE. The cleaning procedure calls for keeping the parts in the condensing part of the machine until dry. And OSHA survey was conducted to ensure compliance and we were well within limits.

c. What are the benefits to your business of TCE?

Critical to the cleaning process for all products. Could be compared to oil in a car engine.

4) Exposure reduction for vapor degreasing
a. What are your experiences with:

i. Installing or updating ventilation and local exhaust
ii. Installing or operating other engineering controls
iii. Equipment changes to reduce exposures
iv. Monitoring worker exposures to chemicals in the air
v. Air-supplied respirators
vi. Other personal protective equipment
b. If you have changed or updated your exposure reduction technology or methods, how long did that process take?

Our update to the existing equipment took 2 years including research, evaluation, compliance review of the equipment, installation and implementing policies.

c. What do you do to comply with OSHA standards for TCE?

The equipment we purchased was certified as compliant, and OSHA testing was done to verify the operator exposure.

5) Substitutes and alternatives:

a. How do you know which chemicals are in the products you are using?

We use commercially pure TCE.

b. What are the trusted sources of information for you about chemicals you use?

MSDS and research into best practices.

c. Have you tried using alternative chemicals or methods for degreasing? What were the results?

We made an extensive evaluation of the substitutes prior to investing in the current equipment. Aqueous cleaning left stubborn residuals that were difficult to remove and did not achieve desired results. The non-aqueous alternatives can be 10 times more expensive and therefore not usable. In addition, it would appear that the more effective solutions such as 1-bromopropan, methylene chloride, and perchloroethylene, are also health hazards, some with lower OSHA Pel limits than TCE. There is a very high cost and risk of implementing a new chemical cleaning process that may be just as hazardous and then further regulated in the future.

i. Please discuss alternative methods to vapor degreasing as well as alternative solvents or equipment in your vapor degreasing process
ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?

There are no practical alternatives to TCH or Vapor Degreasing available to Kearflex at this time.

iii. If you have tried or switched to alternative chemicals or methods, how long did that process take? Did it require equipment modifications or new equipment purchases?
d. If TCE could no longer be used for vapor degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
e. If TCE could no longer be used for vapor degreasing and you were to choose another solvent, would you have to make specific changes to your system to meet emission requirements?
i. What would those changes be?
ii. What would it cost to make those changes in order to be compliant with emissions requirements? [Please note that these would be the changes associated with meeting emission requirements and not those associated with converting or otherwise updating systems to operate using the new solvent.]

6) Regulatory options
a. Which of the regulatory options presented today would you recommend?

Elimination of TCE is a direct threat to the survival of Kearflex Engineering.

Achieving the 0.0004 exposure limit with full time protective equipment, and replacement of the degreasing equipment, would be prohibitively expensive with no assurance that compliance could be achieved in the real world. In addition, if TCE is eliminated in the future, the investment would be a total loss. The proposed exposure limit is 250,000 times lower that the current OSHA limits and 25,000 lower than the ACGHI limit of 10 ppm.

Both of these options could close out our business.

An option for a lower limit than the current 100 ppm based upon good industrial hygiene is not offered at this time. The engineering controls we use (section 3b) in conjunction with a machine we consider to be well designed should allow compliance with a lower limit without the loss of our business.

At a minimum, gradually lowering the exposure limits would drive improving workplace safety and allow technology time to develop alternatives that are practical for industry.

b. Cost estimates: In your experience, are the cost estimates reasonably representative for both options presented?

Both options are prohibitively expensive for Kearflex. The 0.0004 exposure limit is equivalent to banning TCE.

SBAR Panel Discussion Questions: TCE in Vapor Degreasing
c. Can you think of ways to add flexibility to this rulemaking for your small businesses?

d. How do you learn about EPA regulations and what you should do to comply?

e. What is the best way to reach out to members of your industry?

Kearflex appreciates the opportunity to participate in the SBAR process as these regulations are of critical importance to our company.

Sincerely,

Brian Peskin, VP 6/22/2016.

Contact information:
7) Nathaniel Jutras, RFA/SBREFA staff contact
EPA Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov

3. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/28/2016 comments)

Kearflex Engineering
66 Cypress Street
Warwick, RI 02888
Brian Peskin, VP 6/28/2016

TSCA Section 6 Proposed Rule: TCE in Vapor Degreasing

1) How many workers are:
a. In your facility?
20

b. Involved in vapor degreasing when the system is in use?
About 12 employees operate the degreaser at random depending on activity with no more than 2 hours in the vicinity of the machine per day total. 95% of the use would be by 5 employees with no more than 2 hours for any one person. The remaining 7 employees such as engineers and managers use the degreaser on an incidental basis for non-standard operations such as cleaning parts during the repair of equipment.

c. Not performing vapor degreasing but near the system and involved in other tasks (bystander workers)?
0 - 5 Employees in the room. Most common full time occupancy is 2. No work station is closer than 10 feet.

2) Duration:
a. How frequently (# of days per month) does your facility operate a vapor degreasing system?
For our business the machine operates 8 hours a day for 50 weeks per year. This is standby operation.

b. How long (# of hours) is the system in operation during each day it operates?
The machine is used for cleaning an average of 3 hours per day. As the process is timed and semi-automatic, operator presence at the machine location is an average of 30 minutes per day. The machine can run 4 to 6 cleaning cycles per hour and only requires a few minutes to load and unload.

c. How long (# of hours) are the workers and bystander workers in the vicinity of the degreasing equipment/system when in use?
Operator presence at the machine location is an average of 30 minutes per day.

3) Controls and current work practices related to vapor degreasing:
a. How old are the degreasing systems you use?
8 Years

i. If you have upgraded your system, when was that?
The last update was 6/2008. We purchased a new and compliant vapor degreasing machine. Procedures were established, and training and operator certification was performed. There are weekly and monthly operational tests performed and recorded to ensure the unit is functioning correctly.

ii. If you have not upgraded your system, are you planning to? If so, when and why?

b. What type of equipment (e.g., open top, closed loop, vacuum) are you currently using? Please provide manufacturer specifications or a schematic of the equipment system you are using.
The system has a sliding top that is closed during degreasing and when not in use. The top slides open and a small crane slowly lowers the parts in a basket into the degreaser and closes the door. After timed submersion in the degreasing fluid, the crane lifts the parts into a cold drying zone within the machine for a "dwell" period. Once allowed to dry, the top is opened and the parts are lifted out. The operator is not touching liquid TCE - the parts are dry upon removal. Vapor is condensed and kept within the machine. The operators are usually not present during the timed cleaning cycle.

Although classified as "open top" the machine has a sliding cover and a cold vapor barrier to contain vapors.

Diagrams are at the end of the document.

c. What kind of controls and best practices do you currently employ to inform workers of hazards and protect them from exposure to TCE? Do you use any or all of the following:
i. Closed equipment like closed loop vapor degreasers
The degreaser has a sliding top that is closed except for when parts are lowered into the machine by the crane, and removed by the crane. Vapor is contained by a refrigerated cold layer.

ii. Engineering controls like local exhaust ventilation

The equipment is in a large room with a high ceiling that is well ventilated. All other operator stations are well away from the unit.

The machine cover, the crane speed, and the cold temperature zone is measured regularly, and records are kept. The degreaser boiler heater will not operate without the cold system active.

No one operator is allowed to use the machine for more than 2 hours per day.

iii. Personal protective equipment. i.e., respirators

iv. Worker training
Only trained personnel are allowed to operate the degreaser.

v. Other methods to reduce worker exposure
No one operator is allowed to use the machine for more than 2 hours per day.

d. What do you do to comply with the OSHA requirements that apply to your use of TCE?

OSHA requirements remain unchanged at 100ppm TWA for an 8 hour day. We measured the exposure levels with the original equipment at 12ppm per hour. The new machine should be well under 10ppm per hour. By limiting operator exposure to 2 hours max and using a worst case level of 10ppm per hour, the TWA for an 8 hour day would be 2.5ppm or less.

This gives us a 40:1 margin with respect to the OSHA requirement. In practical operation, actual operator time at the degreaser is 0.5 hours per day, which would place the 8 hour TWA below 1 ppm.

4) Monitoring for worker exposure levels:

a. Have you monitored for worker exposures?

We had an air sample taken in April 2008 before the improved machine was installed and the operator and local air samples were very low. The operator TWA PEL was 0.09ppm and the area YWA PEL was 0.21ppm. These numbers are well below the 2.5ppm we use for our safety calculations.

i. If you have, have you collected personal or area samples?

Area and personal samples.

ii. What type of monitoring equipment have you used?

Air sampler.

b. Do you have monitoring data on the exposure levels that you can share with us, e.g., industrial hygiene monitoring reports or company collected data?

The operator TWA PEL was 0.09ppm and the area YWA PEL was 0.21ppm.

Comments:

An option for a lower limit than the current 100 ppm based upon good industrial hygiene is not offered at this time. The engineering controls we use in conjunction with a machine we consider to be well designed should allow compliance with a lower limit without the loss of our business.

At a minimum, gradually lowering the exposure limits would drive improving workplace safety and allow technology time to develop alternatives that are practical for industry.

For companies like Kearflex, implementing the ACGHI limit of 10 ppm over a 10 year period would not require additional investment. We are compliant with the current regulations for vapor degreasers, and expect similar results from other small companies that are using similar equipment.

Kearflex appreciates the opportunity to participate in the SBAR process as these regulations are of critical importance to our company.

Sincerely,

Brian Peskin, VP 6/28/2016.

Contact information:
7) Nathaniel Jutras, RFA/SBREFA staff contact
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202-564-0301
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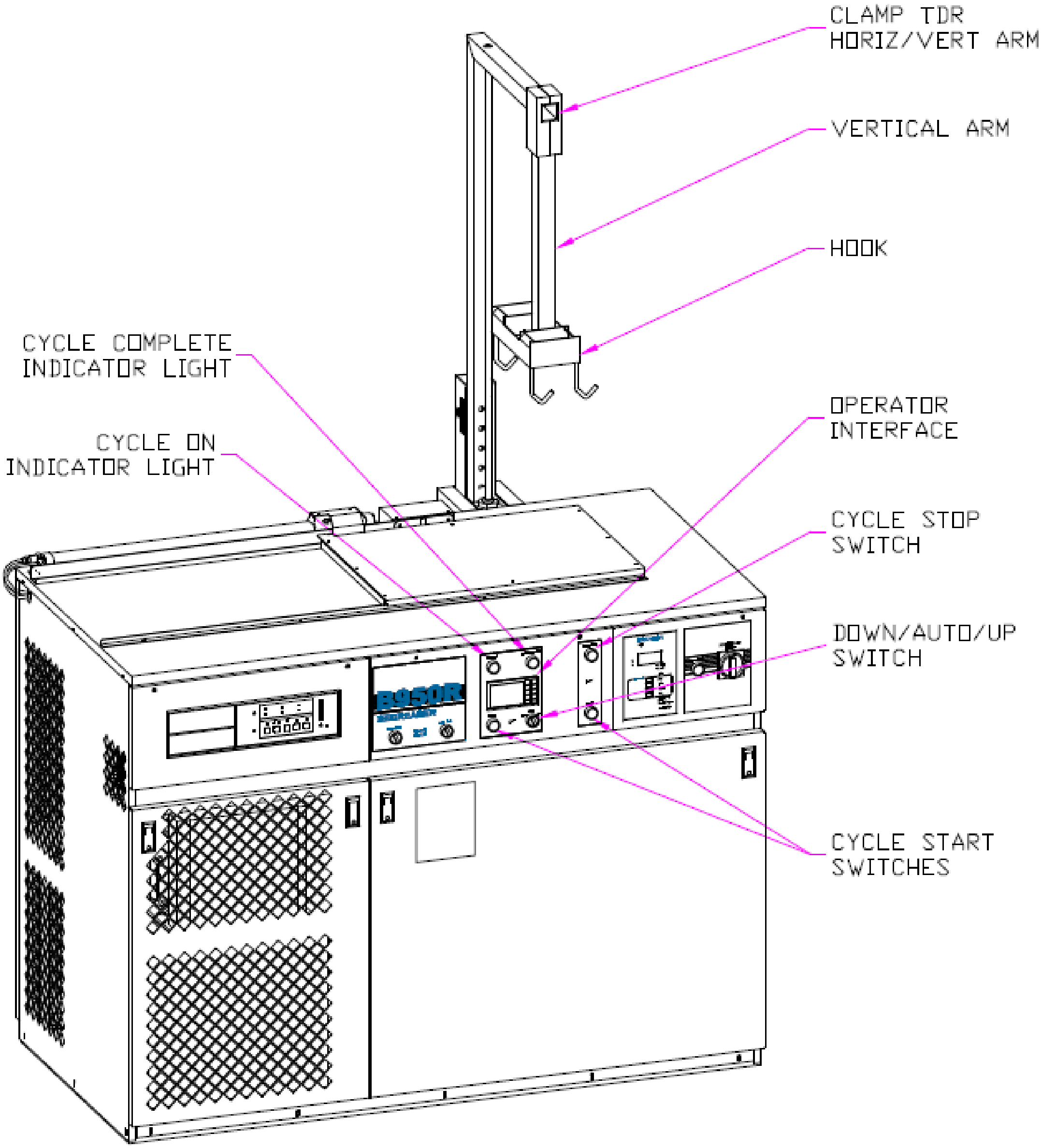
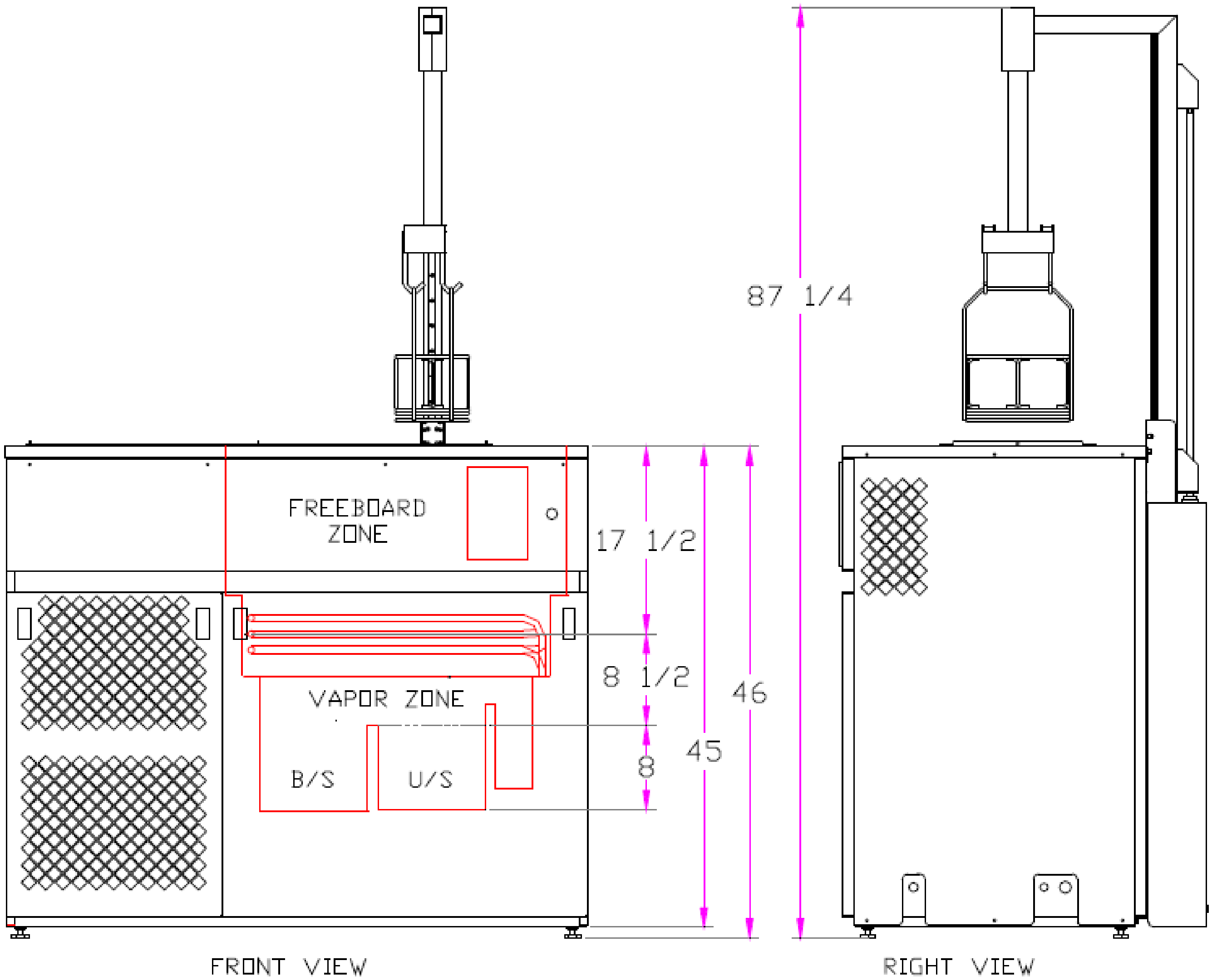


Degreaser with sliding cover and parts crane.
Door is open to move parts in and out.
The crane speed is slow to prevent disturbance of the TCE vapor.
Cleaning in the machine is timed and the operator does not need to stay by the unit.



Cutaway view.
The vapor zone is deep within the unit.
The B/S is the boiling sump and the U/S us the ultrasonic cleaning sump.
The Freeboard Zone is very cold to trap and return any vapor that rises.

4. Marquette Tool & Die Co., Gerry Richardson, from St. Louis, MO

From: Gerry Richardson [mailto:grichardson@marquettetool.com]
Sent: Friday, July 01, 2016 8:10 AM
To: Jutras, Nathaniel <Jutras.Nathaniel@epa.gov>
Subject: RE: Reminder Regarding Your Input by July 1 and Instructions for Submitting CBI

Nathaniel,

Per our telephone conversation, our usage of TCE is only 2 1/2 % of our permitted amount. All permits and reports are up to date.

Gerry Richardson
Marquette Tool & Die Co
3185 S. Kingshighway Blvd
St. Louis, MO 63139
314-771-8509

5. McMillan Electric Company, Floyd Ankrum, Plant Engineering Manager, from Woodville, WI

From: FAnkrum@MCMILLANELECTRIC.COM
To: Jutras, Nathaniel
Subject: Fw: SBAR Panel for TCE Vapor Degreasing
Date: Tuesday, June 28, 2016 2:02:49 PM
Attachments: DOC062816.pdf

Jutras,

Response to email request.

1. a) 217 employees
   b) Involved in vapor degreasing system when in use? 1 load and unload, 0 involved when in use.
   c) 1 vapor degreaser operator, 3 press operators

2. a) 20-25 or M-F
   b) 8
   c) 7.5

3. a) 1 system was purchased in 2000
   i) In 2003 we added to load station enclosure length and track making system completely automatic. Operator loads basket then pushes a button and does other tasks and returns to remove parts from basket. The tank also has covers that will open and close during cleaning cycle.
   b) Closed top as well as load station enclosure. See pdf below for manufacturer and schematic of equipment

   c) System has closed load station enclosure, closed chemical doors, chiller coils to contain chemical on 24/7, SDS available, PM program to closely monitor stabilization of chemical, As mentioned added 12' to load station so operator will load parts 8' away from end of tank and system is completely automated with the push of button.
   d) We have PM's for this equipment. Weekly check the temperature at the midpoint of the cold air blanket and record temperature on form and check chiller if correct temp is not recorded. Yearly Submit exceedance report to DNR, submit certification of SDS to Baldwin DNR office and check for OSHA compliance with trichloroethylene vapor limits. Every 30 days preform a visual inspection of vapor cover, hoist speed is monitored and record solvent usage for solvent emission report. Every 15 days take solvent sample to check solvent condition and add stabilizer as needed.

4 a) Yes we have monitored
   b) Yes area samples and personal
   c) Quarterly charcoal tube samples done in house. 4/30/15 Hired Industrial Hygienist to collect samples and have the results processed a the Wisconsin Occupational Health Laboratory using WOHL method WG006.8

Our results:

~6717893.pdf - Adobe Reader

there is no exposure to TCE for the time not sampled.

Table 3: Airborne Concentrations of TCE

Sample	Volume	Mass TCE Collected	Concentration for Time Sampled	8-Hour Time Weighted Average Concentration
	Liters	mg	ppm	ppm
Debbie Lorenz	92.46	55	11	11
Carol Schlosser	93.12	52	10	10
Ken Deppe	92.92	75	15	14
Ken Deppe STEL 1	3.05	2.9	18	NA
Ken Deppe STEL 2	3.45	4.7	25	NA
Washer Area	92.26	82	18	16
Blank	NA	<0.0087	NA	NA

Legend
Mg – Milligrams of TCE
PPM – Parts per million

3

Permissible OSHA levels

3325 Fear Street | Eau Claire, WI 54701 | 715.379.5621

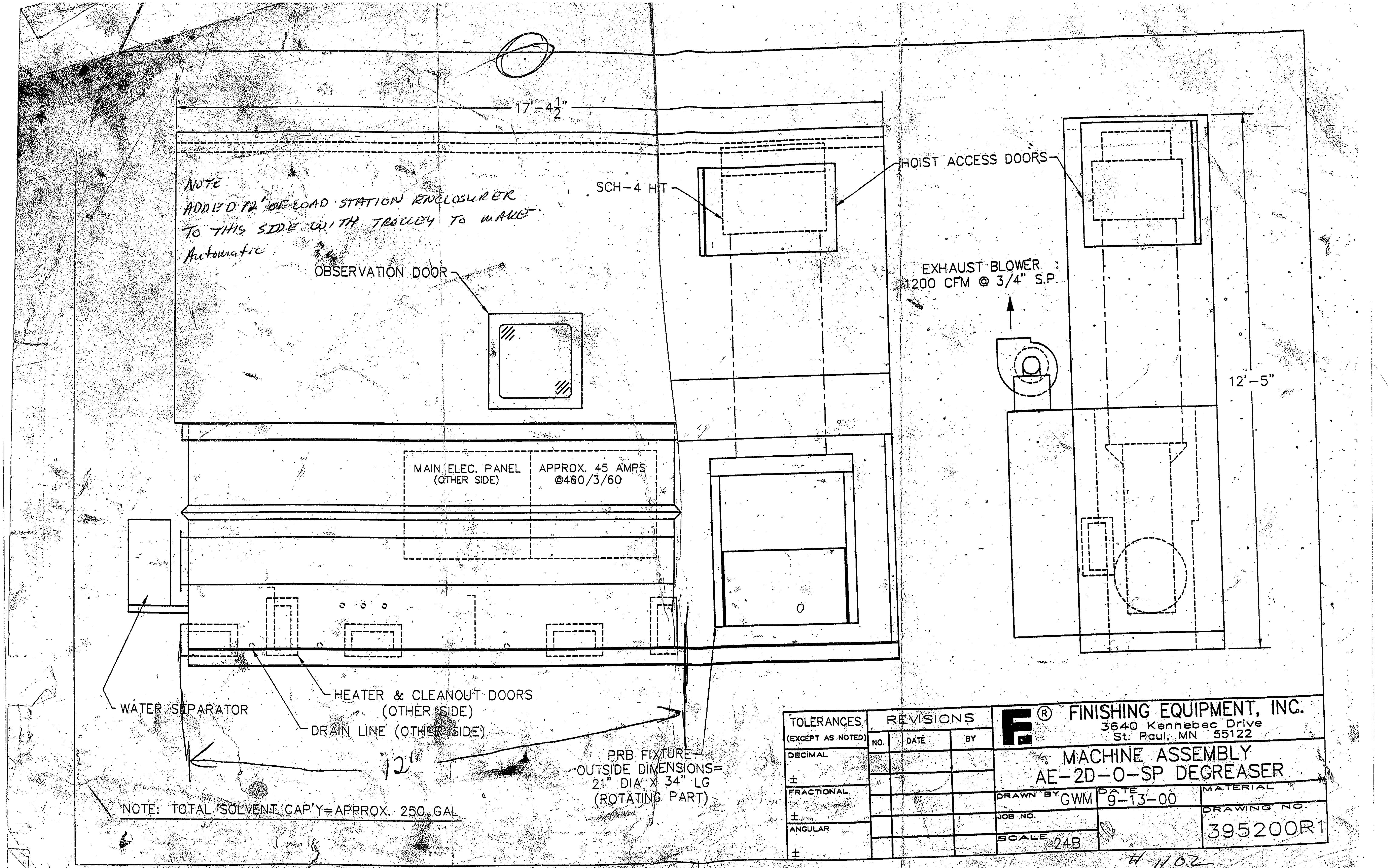
Table 1: Exposure Limits for TCE

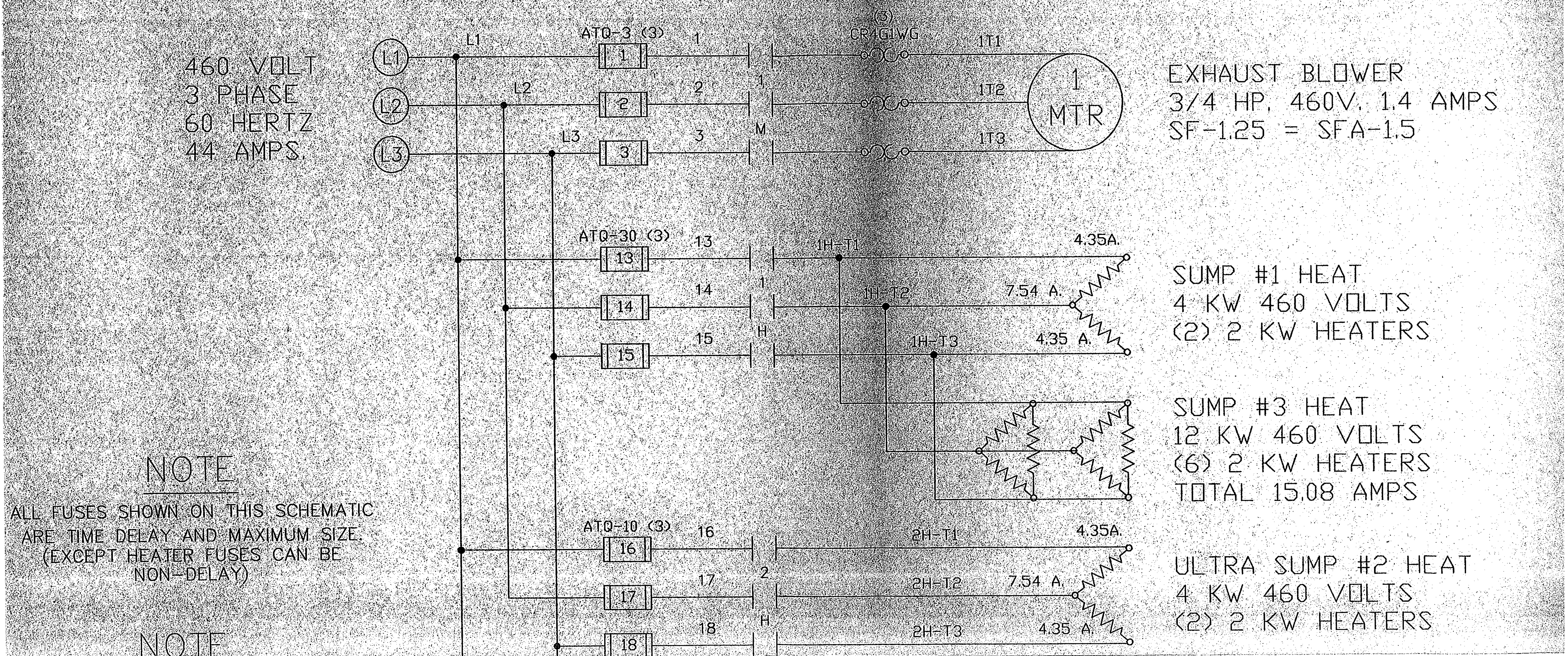
Source	Time	Exposure Limit
OSHA PEL for TCE	8 hours	100 ppm
OSHA PEL for TCE	15 minutes	200 ppm
OSHA PEL for TCE	5 minutes in 2 hours	300 ppm
ACGIH TLV for TCE	8 hours	10 ppm
ACGIH TLV for TCE	15 minutes	25 ppm

Purpose

Parts used in motor case assemblies are washed in TCE prior to being assembled. The parts washer was running nearly the entire time the sampling was conducted. Three employees were present in the area for nearly the entire time sampling was conducted. One employee, Ken Deppe was the operator of the parts washer. Two other employees Debbie Lorenz and Carol Schlosser were working with newly washed parts to bend and press them for future use in the assembly process.

Floyd Ankrum
Plant Engineering Manager
McMillan Electric Company
400 Best Road
PO Box 107
Woodville, WI 54028
Phone: (715) 698-7124
Fax: (715) 698-2297
Email: fankrum@mcmillanelectric.com


17'-4 1/2"
NOTE: ADDED 12' OF LOAD STATION ENCLOSURER TO THIS SIDE WITH TROLLEY TO MAKE Automatic
SCH-4 HT
HOIST ACCESS DOORS
OBSERVATION DOOR
EXHAUST BLOWER 1200 CFM @ 3/4" S.P.
12'-5"
MAIN ELEC. PANEL (OTHER SIDE)
APPROX. 45 AMPS @460/3/60
WATER SEPARATOR
HEATER & CLEANOUT DOORS (OTHER SIDE)
DRAIN LINE (OTHER SIDE)
12'
PRB FIXTURE OUTSIDE DIMENSIONS= 21" DIA X 34" LG (ROTATING PART)
NOTE: TOTAL SOLVENT CAP'Y=APPROX. 250 GAL
TOLERANCES (EXCEPT AS NOTED)
DECIMAL ±
FRACTIONAL ±
ANGULAR ±
REVISIONS
NO.
DATE
BY
FINISHING EQUIPMENT, INC.
3640 Kennebec Drive
St. Paul, MN 55122
MACHINE ASSEMBLY
AE-2D-0-SP DEGREASER
DRAWN BY GWM
DATE 9-13-00
MATERIAL
JOB NO.
DRAWING NO.
395200R1
SCALE 24B
H 1102


460 VOLT
3 PHASE
60 HERTZ
44 AMPS
L1
L2
L3
ATQ-3 (3)
1
2
3
(3)
CR4G1WG
1T1
1T2
1T3
1
MTR
1
M
EXHAUST BLOWER
3/4 HP, 460V, 1.4 AMPS
SF-1.25 = SFA-1.5
ATQ-30 (3)
13
14
15
1
H
1H-T1
1H-T2
1H-T3
4.35A.
7.54 A.
4.35 A.
SUMP #1 HEAT
4 KW 460 VOLTS
(2) 2 KW HEATERS
SUMP #3 HEAT
12 KW 460 VOLTS
(6) 2 KW HEATERS
TOTAL 15.08 AMPS
NOTE
ALL FUSES SHOWN ON THIS SCHEMATIC ARE TIME DELAY AND MAXIMUM SIZE. (EXCEPT HEATER FUSES CAN BE NON-DELAY)
ATQ-10 (3)
16
17
18
2
H
2H-T1
2H-T2
2H-T3
4.35A.
7.54 A.
4.35 A.
ULTRA SUMP #2 HEAT
4 KW 460 VOLTS
(2) 2 KW HEATERS
NOTE

6. Nobert Plating Co., Rob Sickles, C.E.F., from Chicago, IL

Nobert Plating Co.

SBAR Panel for TCE Vapor Degreasing under TSCA Section 6a

Questions from e-mail dated 6/27/2016

1) How many workers are:

a. In our facility?
Approximately 25 at any time.

b. Involved in Vapor degreasing when in use?
One to two persons involved in process and possibly two near the unit.

2) Duration:

a. How frequently is the System used?
Approximately 15 days per month.

b. How long is System in operation during any given day?
Approximately 6 hours.

c. How long are workers/bystanders in vicinity?
Similar amount of time as in operation

3) Controls and current work practices:

a) Age of degreasing system?
Unit was purchased new in 2013 upgrading from and older system that used TCE. The new system uses nPB.

b) Type of equipment?
Baron-Blakeslee MLR-280LE manual/open top unit (schematic attached)

c. What do you do to comply with OSHA standards for TCE?
TCE is not applicable as we have switched to nPB in 2013.

General Comments:

We are a job shop metal finisher and a small user of compared to many. The costs to switch over to nPB were considerable (about 60K for the unit and double the chemical costs on an annual basis to run) as many current units that have been in service will not be able to simply “drop in” the alternatives. Upgraded equipment will be needed in most cases to run according the requirements of the replacement to be used. When switching to nPB we found that there were some issues with aluminum castings and castings were not compatible with the nPB. I would guess that for larger users this will be the case across more substrates. This causes the need for further cleaning solutions for those items that may not be compatible. It should also be noted that we now turn down any defense and aerospace work that specifies Tri-Chlor. There is no simple "drop in" replacement and I think many points in the letter sent by the PMPA to address the committee should be noted as they apply across all the industries involved.

Respectfully,

Rob Sickles, C.E.F.
Vice President
Nobert Plating Co.
340 N. Ashland Ave
Chicago, IL 60607
rsickles@nobertplating.com
rsickles@npc1903.com
312-421-4040

Baron·Blakeslee
A Wholly Owned Subsidiary of Service Filtration Corporation

Baron-Blakeslee SFC, Inc. 2900 MacArthur Boulevard, Northbrook, IL 60062-2005
Sales: 502-541-9810, Corporate: 847-509-2910, Fax: 847-509-2908
www.baronblakeslee.com

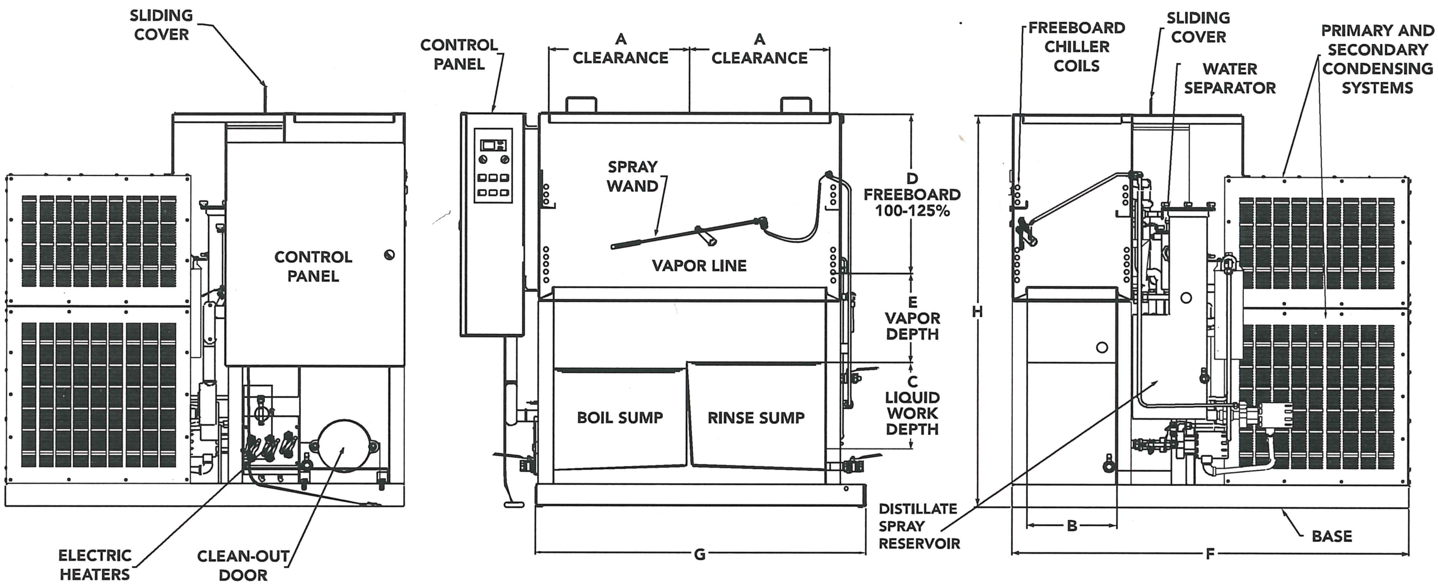
The M Series Precision Vapor Degreaser is the top selling vapor degreaser worldwide and is our most versatile low-emission precision cleaning system. The M Series is complete with all standard features required to meet U.S. EPA NESHAP regulations and even the most stringent local environmental regulations.

Configurations Available: Vapor Spray, Immersion/Vapor Spray, Ultrasonic Immersion/Vapor Spray

Standard M Series Precision Vapor Degreaser Features Include:

- 100% - 125% Freeboard Ratio*
- Direct Expansion Refrigeration For Primary Condensation (R-134a)
- VAPORTRAP Sub-Zero Freeboard Refrigeration (R-404a)
- Automatic Hot Gas Bypass Defrost For VAPORTRAP
- Stainless Steel (304) Material For All Solvent Wetted Surfaces
- Stainless Steel Condensing Coils (304) For All Refrigeration Systems
- Magnetic Drive Spray Pump With Foot Switch Operated Spray Lance
- Magnetic Drive Recirculation Pump and Filtration System*
- Four Side Tank Insulation
- Ultrasonic Transducer and Digital Generator Systems*
- Stainless Steel (304) Glide Cover
- Stainless Steel (304) Filter Housing With Cartridge Filter*
- Stainless Steel (304) Water Separator
- All Welding In Accordance With ASME Section IX: For TIG Welding
- All Welds Passivated, Tank Sections Welded Inside & Out
- Solvent Vapor Control
- High Temperature Control
- Digital Liquid Temperature Control
- Low Level Control
- Vapor Up Control
- User Selectable Controls For Multi-Solvent Capability
- UL Listed Electrical Panel
- 50 Hz / 60 Hz Compatibility
- Two Sets Of Operation, Maintenance & Instruction Manuals
- Full Technical Support
- One Year Limited Warranty
- Many Standard & Custom Material Handling Options
- Manufactured In Williamstown, WV, USA

** Model Dependent.*



GENERAL TECHNICAL SPECIFICATIONS - M SERIES PRECISION VAPOR DEGREASERS

MODEL NUMBER	DIMENSIONS IN INCHES (Approx.)								SOLVENT CAPACITY IN GALLONS			LOAD CAPACITY (Lbs Stl/Hr nPB Solvent)	DISTILLATION RATE (GPH/ nPB)	PRIMARY REFRIG. UNIT (HP) (R134A)	VAPOR TRAP REFRIG. UNIT (HP) (R401A)	ELECTRIC HEATER (KW)	STANDARD VOLTAGE 60HZ (FLA)	SHIPPING WEIGHT (APPROX.)
	INSIDE TANK					OVERALL												
	LENGTH (A)	WIDTH (B)	HEIGHT RINSE SUMP (C)	HEIGHT FREE-BOARD (D)	HEIGHT VAPOR ZONE (E)	WIDTH FT - BK (F)	LENGTH L TO R (G)	HEIGHT (H)	BOIL TANK	RINSE TANK	SPRAY TANK							
MVR-215	21		N/A		19				7.5	N/A							230/1 (21)	900
MLR-120	10	12	10	18	10	32	62	41	5.5	5.5	2.5	50	3.5	1/2	1/2	1.5	230/1 (21)	925
MSR-120	10		10		10				5.5	5.5							230/1 (29)	950
MVR-444	37		N/A		21				9	N/A							230/1 (42)	2150
MLR-216	18	12	12	21	12	54	45	48	18	13	3	300	10	2	1-1/4	4.5	230/1 (42)	2200
MSR-216	18		12		12				18	13							230/1 (50)	2250
MVR-574	41		N/A		27				27	N/A							230/3 (49)	2400
MLR-280	20	14	16	22	16	70	48	56 1/2	22	16	9	750	15	3	1-1/2	9	230/3 (50)	2450
MSR-280	20		16		16				22	16							230/3 (66)	2500
MVR-980	49		N/A		33				47	N/A							230/3 (52)	2800
MLR-480	24	20	20	24	20	77	54	72	62	35	9	1000	15	3-1/2	2-1/4	9	230/3 (54)	2850
MSR-480	24		20		20				62	35							230/3 (70)	2900
MVR-1464	61		N/A		46				64	N/A							230/3 (85)	3200
MLR-720	30	24	24	28	24	90	64	84	123	86	12	1200	35	7 1/2	2-1/4	18	230/3 (85)	3250
MSR-720	30		24		24				123	86							230/3 (115)	3300

Baron-Blakeslee SFC, Inc. 2900 MacArthur Boulevard, Northbrook, IL 60062-2005 **Sales: 502-541-9810, Corporate: 847-509-2910, Fax: 847-509-2908**
www.baronblakeslee.com

BBMSeries0410rev1

7. Parts Cleaning Technologies, David Crandell, President, from Redford, MI

PARTS CLEANING TECHNOLOGIES

26400 Capitol
Redford, MI 48239
313.952.2646

June 30, 2016

Nathaniel Jutras
U.S. Environmental Protection Agency
Regulatory Management Division

RE: Small Entity Representatives (SER) Proposed Rulemaking under TSCA Section 6(a) for Trichloroethylene (TCE) in Vapor Degreasing

Dear Nathaniel,

Thank you for inviting me to participate as an SER in the proposed rulemaking for TCE. I will provide an industry prospective both as an SER and a distributor of cleaning chemistries (including TCE) and manufacturer of parts cleaning equipment (including vapor degreasers using TCE). I have been involved in this industry for twenty six years, including the last fifteen years as the owner of Parts Cleaning Technologies (PCT). PCT distributes chlorinated, brominated and aqueous chemistries for the parts cleaning industry. In addition, PCT designs and builds parts cleaning equipment for the chemistries mentioned above. During the past 20 years we have converted numerous companies from TCE to NPB and /or aqueous cleaning systems. My comments on the proposed regulations and the underlying analysis performed by the EPA are summarized below. The majority of my comments will make reference to the presentation titled "Rule making under the Toxic Substances Control Act (TSCA) for the use of Trichloroethylene (TCE) in Vapor Degreasing."

Industry Overview

From the 1940's through the early 1990's chlorinated solvents and vapor degreasers were the main cleaning process for cleaning metal fabricated parts. Chlorinated solvent cleaning processes were 90% of the industry. Companies started with TCE converted to 1,1,1- trichloroethane and in some cases Freon-113. Due to ozone-depleting issues many companies converted back to TCE.

Advantages of TCE have been and remain its ability to clean a wide range of lubricants, over a wide divergent array of geometric part size and configuration and over a wide range of part substrates, in a small footprint with the least amount of indirect costs such as labor and utilities.

Today chlorinated solvents represent less than 5% of the industry. During the past twenty years, the EPA has implemented rule making that has significantly changed the industry. The EPA rules significantly reduced emissions exiting the facilities and had a profound impact on reducing exposures to workers within the facility. At each phase of rule making our industry has worked in conjunction with the EPA to implement rules that significantly reduced emissions and worker exposure.

In 1994 the EPA, adopted a National Emission Standards for Hazardous Air Pollutants; Halogenated Solvent Cleaning (NESHAP). This rule focused exclusively on the operation of various types of vapor degreasers. The NESHAP outlined specific rules for operating procedures, equipment design and controls, obtaining an air permit to operate the machine, calculation of annual emissions and detailed record keeping and reporting to ensure compliance. This rule resulted in an 80%-90% reduction in emissions in vapor degreasers using chlorinated solvents (primarily TCE).

The second EPA rule that had a significant reduction in emissions and worker exposure was the 2007 revision of the NESHAP. I personally participated with the EPA in developing this rule. This rule further restricted emissions and worker exposure by placing an annual facility restriction emission level of 10 tons per year for TCE, regardless of facility size, number of vapor degreasers and even if the existing machines were in compliance with the 1994 NESHAP. Some industries were exempted.

The impact of these two rules reduced TCE consumption and emissions and worker exposure by 95% since 1998.

Today less than 5% of the industry uses TCE. The machines are tight and rarely have more than one operator and are rarely used 8 hours a day. The companies and applications that could convert to another cleaning process have done so.

Cleaning Process Conversion

The conversion of a cleaning process for a manufacturer is expensive, time consuming and complicated. Customers have implemented strict cleaning specifications so the part can perform. In the past, the cleaning specification was "cleaned by TCE in a vapor degreaser". The vast majorities of the cleaning substitutes for TCE do not clean as well as TCE, are more expensive to purchase and require a large capital investment for a cleaning process that is less productive.

To change the cleaning process, a cleaning specification must be developed. In other words how clean does a part have to be to perform? Developing a cleaning specification could take from 6 months to 4 years. For a typical manufacturing customer that purchases a noncritical part the time period to develop a new cleaning specification is 9 months. Medical devices, aerospace, electronics for military defense are industries with very stringent cleaning specifications.
For medical instruments that come in contact with the human body, the time period is four years to get FDA approval. Aerospace approval on critical parts is four years. An electronic part for military approval is three years.

After the cleaning specification is approved, equipment design, build, installation, building modification if required and local permits could take another two years.

Production Substitution

The vast majority of the industry has already converted to an alternative cleaning process for TCE. The majority of the industry has converted to an aqueous chemistry cleaning process. Typically, aqueous cleaning requires new equipment that is significantly larger, more expensive to operate, less productive, and may require multiple machines to replace one vapor degreaser. Easy to clean parts with minimal cleaning specifications have already converted to aqueous. Typical machine cost for an aqueous cleaning process is $250,000 replacing a $75,000 vapor degreaser.

Drop in replacements suggested by the EPA such as other chlorinated and brominated solvents are not viable alternatives. These replacements are under review by the EPA to determine health effects. In addition the replacement products operate at different temperatures and are less stabile compared to TCE.

Non drop in alternatives solvents such as hydrofluorocarbons, hydrofluoroethers and hydorofluoroolefins are not viable replacements. These products boil at much lower temperature (temperature is a critical part of cleaning) and as a result are harder to keep in the machine increasing worker exposure. In addition, they don't clean without adding a chlorinated derivative – typically trans-1, 2-dichloroethylene (sometimes as much as 70%), which is flammable. These products are 10 times more expensive per pound and the customer uses significantly more product because of the lower boiling causing more solvent to leave the machine and expose the worker.

Estimated number vapor degreasers using TCE in the US

On slides 8 and 9 the EPA estimates approximately 2,600-6,200 vapor degreasers in use today. The actual number of vapor degreasers in use is significantly lower. The EPA states that 255,000,000 pounds of TCE is used in the United States (US) annually. The EPA estimates that 15% of the TCE used in the US goes into vapor degreasing. Based on discussions with US producers of TCE, 5% of TCE (or 12,500,000 pounds) used in the US goes into vapor degreasing. In 2008, the EPA issued NESHAP limiting emissions per facility to 10 tons or 20,000 pounds per year. Dividing 12,500,000 pounds of TCE used in the US by the maximum amount of pounds of emission allowed per facility equals 637 facilities using TCE in the US. If you assume that all facilities emit 10,000 pounds per year (not realistic based on my customer base) 1,274 facilities use TCE. I believe the number of facilities using TCE is less than 800. These estimates could be verified from the data already required to be reported to EPA under the NESHAP.

Vapor degreaser type and uses

Slides 9 and 21 refer to in line degreasers, closed degreaser and open top degreasers. All vapor degreasers have covers. Small degreasers referred to as "open tops" are required by the NESHAP to have covers, extended walls, chillers, engineering controls, operating procedures and quarterly reporting to minimize emissions. The "95% reduction in emissions by converting "open tops" to closed machine" referenced on slide 21 has already occurred due to compliance with the NESHAP.

Most in line vapor degreasers are large capacity machines such as for cleaning razor blades. These large machines operate in a separate room without operators. Emissions are captured and run through a carbon absorption system which removes 95 % of the TCE from the air streams. Carbon absorption is a method allowed under the NESHAP. Vacuum degreasers are very limited in application. Vacuum degreasers are expensive ($400,000 - $2,000,000), have a large footprint and limited production capacity (normally two cycles per hour).

Number of operators and exposure limits

Slide 9 estimates 5-12 workers per machine.
Slide 18 estimates worker exposure ppm on an 8 time weighted average to be 190 for workers at the vapor degreaser and 145 for workers adjacent to the degreaser.

Based on my customer base and experience in the industry, the average number of workers per vapor degreaser is 1 and the number of workers adjacent to the vapor degreaser is 1 and TWA exposures limits are significantly lower than 190. In addition, the vapor degreaser is operated less than 8 hours per 8 hour shift.

The 2007 NESHAP limited emissions to 10 tons per facility. The rule exempted certain industries; narrow tube, razor blade and aerospace maintenance facilities. I have customers in all three industry segments. The working environments in all of these industry segments are similar. First they all comply with the NESHAP. Second the degreasing operation is in a separate room. Third all vapors from the degreasing operation are captured and processed thru a carbon absorption process which recovers 95% of the TCE vapors in the air stream. Workers are either never in the room or enter to engage an automatic loading system and leave. Worker exposure to emissions in these industry segments is very low.

Over 90% of the vapor degreasers in operation are small units (5 foot by 3 foot by 5 foot or smaller) and are NESHAP compliant as explained above. Most vapor degreasers in my customer base are isolated from the rest of the manufacturing operation, have 1 operator that operates the machine less than 8 hours per day and no adjacent workers. As a service we perform exposure limit testing to our customers. Additionally the human nose can detect 40 ppm. In essence if you can smell the TCE you are above a single exposure of 40 ppm. Visiting customers I rarely smell TCE.

Occupational Safety and Health Administration has determined a person exposure limit (PEL) of 100 ppm for an 8 hour time weighted average (TWA).

American Conference of Governmental Industrial Hygienists (ACGIH) recommends a TLV-TWA of 10 ppm.

Both limits are disclosed to the industry on the Safety Data Sheets (SDS) supplied with TCE. All of our customers have a SDS on site.

In summary I believe over the past 20 years the EPA has already had a tremendously favorable impact in reducing emissions and worker exposure to TCE. The EPA and industry have worked in conjunction to develop responsible rule making for limiting exposure to TCE under the Clean Air Act. I applaud the EPA for being the driving force in improving operation conditions in our industry. I thank the EPA for allowing industry to once again participate in new proposed rulemaking for TCE.

I am 100% agreement with the responses prepared by Mr. Miles Free Director, Industry Research and Technology, Precision Machined Product Association and incorporate his comment by reference in case I missed a salient point.

My own conclusion is that the EPA has had a positive impact on our industry and has historically incorporated our comments. I know this to be true since I participated in the 2007 NESHAP amendment. I believe the actual experience in the field today is significantly better than portrayed in the current EPA analysis. I believe worker exposure is significantly lower, operating environments are significantly improved, machine are enclosed and have better engineering controls than is being presentation in the data. Perhaps the data points for worker exposure in the EPA analysis are from a time period before all the industry improvements were made. However, based on my personal knowledge from visiting and interacting with customers, I know the worker's exposure limits are significantly less than displayed in the EPA analysis. Additionally, there are significant fewer vapor degreasers in operation and significantly fewer workers operating at or near the machine than reported in the EPA analysis. Finally, the owners of vapor degreasers that could have converted to a different cleaning process have already done so. The operators of existing vapor degreaser do not have a viable economic alternative that meets their customer cleaning specifications.

My recommendation is to cancel this project and enforce the rules that we already have in place that were developed by EPA with industry input. At the least, rulemaking should not go forward until an accurate baseline assessment of exposure and risk has been developed. The 2014 Work Plan assessment uses worker and bystander exposures based on conditions that predated the NESHAP and thus presents an inaccurate and unduly alarming perspective.

Please also carefully consider the points made in the enclosed paper prepared by legal counsel addressing some of the points of concern in light of the recent TSCA reform, which is incorporated by reference.

Sincerely,

David Crandell /WCN

David Crandell
President
Parts Cleaning Technologies

Enclosure

SER Comments
Impact of New TSCA Legislation

I. Risk Evaluation for TCE in Vapor Degreasing

Toxic Substances Control Act ("TSCA") § 6(b)(4)(F), as revised by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires that the risk evaluation, while it may not consider costs or other nonrisk factors, must among other things:

- "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;"
- "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;" and
- "describe the weight of the scientific evidence for the identified hazard and exposure."

New TSCA § 26(h) requires for each risk evaluation (as "a decision based on science") that "the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models."

<u>Exposure Assessment</u>

As noted by most if not all the SERs, the June 2014 assessment uses the incorrect baseline for exposure to TCE from vapor degreasing, particularly the occupational exposure scenarios. The response to comments states that "EPA/OPPT updated its risk assessment to take NESHAP emission limits into account," but this is not accurate as all of the exposure data in the assessment were collected long before the May 2010 compliance deadline established in the 2007 NESHAP for Halogenated Solvent Cleaning (hereafter "the NESHAP").

By imposing a 10 tons per year limit on TCE emissions from vapor degreasers, the NESHAP changed work practices and greatly reduced both in-facility (occupational and bystander) exposure and fenceline emissions. The reduction was estimated by the SERs to be more than 95%. Moreover, SERs indicated that there are far fewer vapor degreasers still in operation, perhaps 600 to 700, and recommended that EPA determine the number by checking permits. A review of the NESHAP indicates that this information should be available without even that effort, as the following sections require detailed reporting to EPA from 2010 onward, for all covered degreasers,[1] solvent (*i.e.,* TCE) consumption, emissions, controls, and other such information that should enable EPA to develop a very accurate exposure assessment:

> "(e) Each owner or operator of an affected facility shall maintain records specified in paragraphs (e)(1) through (3) of this section either in electronic or written form for a period of 5 years. For purposes of this paragraph, ''each solvent cleaning machine'' means each solvent cleaning machine that is part of an affected facility regulated by this section.
> (1) The dates and amounts of solvent that are added to each solvent cleaning machine.
> (2) The solvent composition of wastes removed from each solvent cleaning machines as determined using the procedure described in paragraph (c)(3) of this section.
> (3) Calculation sheets showing how monthly emissions and the 12-month rolling total emissions from each solvent cleaning machine were determined, and the results of all calculations.
>
> (f) Each owner or operator of an affected facility shall submit an initial notification report to the Administrator no later than May 3, 2010. This report shall include the information specified in paragraphs (f)(1) through (5) of this section.
> (1) The name and address of the owner or operator of the affected facility.
> (2) The address (*i.e.*, physical location) of the solvent cleaning machine(s) that is part of an affected facility regulated by this section.
> (3) A brief description of each solvent cleaning machine at the affected facility including machine type (batch vapor, batch cold, vapor in-line or cold inline), solvent/air interface area, and existing controls.
> (4) The date of installation for each solvent cleaning machine.
> (5) An estimate of annual halogenated HAP solvent consumption for each solvent cleaning machine.

[1] Specifically, "affected facility means all solvent cleaning machines, except solvent cleaning machines used in the manufacture and maintenance of aerospace products, solvent cleaning machines used in the manufacture of narrow tubing, and continuous web cleaning machines, located at a major source that are subject to the facilitywide limits in Table 1 of § 63.471(b)(2), and for area sources, affected facility means all solvent cleaning machines, except cold batch cleaning machines, located at an area source that are subject to the facility-wide limits in Table 1 of § 63.471(b)(2)." 40 C.F.R. § 63.460(i).

> (g) Each owner or operator of an affected facility shall submit to the Administrator an initial statement of compliance on or before May 3, 2010. The statement shall include the information specified in paragraphs (g)(1) through (g)(3) of this section.
> (1) The name and address of the owner or operator of the affected facility.
> (2) The address (*i.e.*, physical location) of each solvent cleaning machine that is part of an affected facility regulated by this section.
> (3) The results of the first 12-month rolling total emissions calculation.
>
> (h) Each owner or operator of an affected facility shall submit a solvent emission report every year. This solvent emission report shall contain the requirements specified in paragraphs (h)(1) through (h)(3) of this section.
> (1) The average monthly solvent consumption for the affected facility in kilograms per month.
> (2) The 12-month rolling total solvent emission estimates calculated each month using the method as described in paragraph (c) of this section.
> (3) This report can be combined with the annual report required in § 63.468(f) and (g) into a single report for each facility."[2]

Michael Jayjock, one of the peer review panelists, concluded: "Clearly, more work is needed on both the exposure and hazard side of this evaluation to tighten up the exposure assessment and to provide further justification or explanation of the exceedingly low HEC99 values used in the MOE analysis."[3] Obviously, the 2014 Work Plan assessment is insufficient on the exposure side.

<u>Hazard Assessment</u>

The Work Plan assessment expressly relies on hazard values derived directly from Johnson *et al.* (2003) to estimate non-cancer risk. Specifically, it states (p. 104):

> "The acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TSCA TCE use scenarios. As indicated previously, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This policy is based on the presumption that a single exposure of a chemical at a critical window of fetal development, as in the case of cardiac development, may produce adverse developmental effects (EPA, 1991).
>
> "After evaluating the developmental toxicity literature of TCE, the TCE IRIS assessment concluded that the fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE exposure (EPA, 2011e).

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[2] 40 C.F.R. § 63.471(e),(f),(g),(h).

[3] https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf.

Thus, EPA/OPPT based its acute risk assessment on the most health protective endpoint (i.e., fetal cardiac malformations; Johnson et al., 2003) representing the most sensitive human population (i.e., adult women of childbearing age and fetus >16 yrs).

"The acute risk assessment used the PBPK-derived hazard values (HEC_{50}, HEC_{95}, or HEC_{99}) from Johnson et al. (2003) developmental study for each degreaser and spot cleaner use scenario. . . . These extremely low values result in margin of exposure ("MOE") values below 10 for almost all the occupational and residential exposure scenarios examined."

A single flawed study should not be the basis for the toxicological value that serves as the basis for regulation. Several other studies, including two GLP-compliant studies conducted under EPA guidelines to support pesticide registration (40 CFR § 870.3700) and Organization for Economic Coordination & Development ("OECD") guidelines (414) have been unable to reproduce the effect seen by Johnson *et al.* (2003).

Johnson *et al.* (2003) reported cardiac effects in rats from research carried out at the University of Arizona and originally published ten years earlier by the same authors.[4] In the earlier-published study, there was no difference in the percentage of cardiac abnormalities in rats dosed during both pre-mating and pregnancy at drinking water exposures of 1100 ppm (9.2%) and 1.5 ppm (8.2%), even though there was a 733-fold difference in the concentrations. The authors reported that the effects seen at these exposures were statistically higher than the percent abnormalities in controls (3%). For animals dosed only during the pregnancy period, the abnormalities in rats dosed at 1100 ppm (10.4%) were statistically higher than at 1.5 ppm (5.5%), but those dosed at 1.5 ppm were not statistically different from the controls. Thus, no meaningful dose-response relationship was observed in either treatment group. Johnson *et al.* republished in 2003 data from the 1.5 and 1100 ppm dose groups published by Dawson *et al.* in 1993 and pooled control data from other studies, an inappropriate statistical practice, to conclude that rats exposed to levels of TCE greater than 250 ppb during pregnancy have increased incidences of cardiac malformations in their fetuses.

Johnson *et al.* (2003) has been heavily criticized in the published literature.[5] Indeed, its predecessor study was expressly rejected as the basis for MRLs by ATSDR in its last TCE Toxicological Profile Update.[6] Moreover, the Johnson *et al.* (2003) findings were not reproduced in a study designed to detect cardiac malformations; this despite employing an

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[4] Dawson, B, *et al.*, Cardiac teratogenesis of halogenated hydrocarbon-contaminated drinking water, J. Am. Coll. Cardiol. 21: 1466-72 (1993).

[5] Hardin, B, *et al.*, Trichloroethylene and cardiac malformations, Environ. Health Perspect. 112: A607-8 (2004); Watson, R., *et al.,* Trichloroethylene-contaminated drinking water and congenital heart defects: a critical analysis of the literature, Repro. Toxicol. 21: 117-47 (2006).

[6] ATSDR concluded that "[t]he study is limited in that only two widely spaced exposure concentrations were used and that a significant dose-response was not observed for several exposure scenarios." Toxicological Profile for Trichloroethylene Update (September 1997), at 88.

improved method for assessing cardiac defects and the participation of Dr. Johnson herself.[7] No increase in cardiac malformations was observed in the second guideline study,[8] despite high inhalation doses and techniques capable of detecting most of the malformation types reported by Johnson *et al.* (2003). The dose-response relationship reported in Johnson *et al.* (2003) for doses spanning an extreme range of experimental dose levels is considered by many to be improbable, and has not been replicated by any other laboratory.[9]

Even the California Office of Environmental Health Hazard Assessment (OEHHA) rejected the study as deficient:

> "Johnson et al. (2003) reported a dose-related increased incidence of abnormal hearts in offspring of Sprague Dawley rats treated during pregnancy with 0, 2.5 ppb, 250 ppb, 1.5 ppm, and 1,100 ppm TCE in drinking water (0, 0.00045, 0.048, 0.218, and 128.52 mg/kg-day, respectively). The NOAEL for the Johnson study was reported to be 2.5 ppb (0.00045 mg/kg-day) in this short exposure (22 days) study. The percentage of abnormal hearts in the control group was 2.2 percent, and in the treated groups was 0 percent (low dose), 4.5 percent (mid dose 1), 5.0 percent (mid dose 2), and 10.5 percent (high dose). The number of litters with fetuses with abnormal hearts was 16.4 percent, 0 percent, 44 percent, 38 percent, and 67 percent for the control, low, mid 1, mid 2, and high dose, respectively. The reported NOAEL is separated by 100-fold from the next higher dose level. The data for this study were not used to calculate a public-health protective concentration since a meaningful or interpretable dose-response relationship was not observed. *These results are also not consistent with earlier developmental and reproductive toxicological studies done outside this lab in mice, rats, and rabbits: The other studies did not find adverse effects on fertility or embryonic development, aside from those associated with maternal toxicity (Hardin et al., 2004).*"[10]

Remarkably, an EPA staff review that was placed in the docket for the Work Plan Assessment reflects similar concerns. First, one staff member dissented over relying at all on the Arizona study:

> "The rodent developmental toxicology studies conducted by Dawson et al. (1993), Johnson et al. (2003), and Johnson et al. (1998) that have reported cardiac defects resulting from TCE (and metabolite) drinking water exposures have study design

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[7] Fisher, J, *et al.*, Trichloroethylene, trichloroacetic acid, and dichloroacetic acid: do they affect fetal rat heart development? Int. J. Toxicol. 20: 257-67 (2001).

[8] Carney, E, *et al.*, Developmental toxicity studies in Crl:Cd (SD) rats following inhalation exposure to trichloroethylene and perchloroethylene, Birth Defects Research (Part B) 77: 405–412 (2006).

[9] "Johnson and Dawson, with their collaborators, are alone in reporting that TCE is a 'specific' cardiac teratogen." Hardin, B, *et al.*, Trichloroethylene and cardiac malformations, Environ. Health Perspect. 112: A607-8 (2004).

[10] California EPA Public Health Goal for Trichloroethylene in Drinking Water (July 2009), at 21 (emphasis added).

> and reporting limitations. Additionally, two good quality (GLP) inhalation and gavage rodent studies conducted in other laboratories, Carney et al. (2006) and Fisher et al. (2001), respectively, have not detected cardiac defects. These limitations and uncertainties were the basis of the single dissenting opinion of a team member regarding whether the database supports a conclusion that TCE exposures during development are likely to cause cardiac defects."[11]

Second, even the EPA staff that agreed with use of the study had little confidence that it supported the dose-response assessment:

> "[A] majority of the team members agreed that the Johnson et al. (2003) study was suitable for use in deriving a point of departure. However, confidence of team members in the dose response evaluation of the cardiac defect data from the Johnson et al. (2003) study was characterized as between 'low' and 'medium' (with 7 of 11 team members rating confidence as 'low' and four team members rating confidence as 'low to medium')."[12]

It is surprising that EPA would consider use of a dose-response value for regulation from a study in which seven of its own scientists expressed "low" confidence, and in which the other four could muster no more than "low to medium" confidence. The same report notes: "In conclusion, there has not been a confirmation of the results of the Johnson et al. (2003) and Dawson et al. (1993) studies by another laboratory, but there has also not been a repeat of the exact same study design that would corroborate or refute their findings." It is understood that the Halogenated Solvents Industry Alliance, Inc. (HSIA), of which Parts Cleaning Technologies is a member, has decided to sponsor a guideline study of TCE developmental toxicity focused on cardiac abnormalities that is intended to help understand the different results seen in the earlier studies. The results of this study, expected later this year, could be an important contribution to a weight of evidence evaluation for TCE as required by TSCA § 26(h).

The concern expressed above is not limited to industry, academic scientists, and other regulatory agencies. One of the peer review panelists, Calvin Willhite, raised serious concerns over the derivation of the non-cancer dose-response:[13]

> "The non-cancer hazard index not only leads to calculation of the lowest equivalent 'safe' concentration of TCE in residential air, but those values are either less than or consistent with background TCE concentrations in United States urban or residential indoor air. As such, any domestic use of TCE in any amount for any use whatsoever will exceed the US EPA's published residential indoor air TCE level (0.21 $\mu g/m^3$). As written, the previously published and current US EPA reports lead to the conclusion that current ambient TCE levels

[11] TCE Developmental Cardiac Toxicity Assessment Update (available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2012-0723-0045).

[12] *Id.*

[13] https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf.

are associated with increased risk for human cardiovascular malformations - yet there are no suggestions from studies of occupational TCE exposures at concentrations 1-2 magnitude of orders greater than ambient pose excess non-cancer health risks to those workers."

With regard to uncertainty, weight of scientific evidence, quality and reproducibility, and other criteria identified in § 26(h), Dr. Willhite stated:

"Question 5-4. Please comment on whether the document has adequately described the uncertainties and data limitations. Please comment on whether this information is presented in a transparent manner.

"The general comments concerning the OPPT and IRIS conclusions on risk for cardiovascular malformations above illustrate the poor weight of evidence assessment carried out in this regard for TCE. The uncertainty attendant to the IRIS hazard identification for cardiovascular terata is so great that it leads to the present OPPT conclusion that all TCE exposures (including background concentrations in US urban ambient and indoor residential air) present increased risk for congenital malformation of the heart and great vessels.

"It is not clear why OPPT relied on the results of the Johnson et al. (2003) study to the exclusion of all other inhalation and oral developmental toxicity studies in rodents and rabbits. If in fact the OPPT is reliant upon only the inhalation data, why is it the Carney et al. (2001), the Schwetz et al. (1975), the Hardin et al. (1981), the Beliles et al. (1980) or the Dorfmueller et al. (1979) study was not used? Why is there no discussion of all of the available developmental toxicity inhalation bioassays in the present analysis?

"Summary

"As submitted, the exposure parameters appear arbitrary (e.g., 0.5 and 1 hr/day) and may have been selected for sake of convenience. The data upon which conclusions put forward by OPPT on risk for developmental toxicity associated with arts and crafts use of TCE are not reliable. Nearly all developmental toxicity studies with TCE in rodents find no sign of teratogenicity (e.g., Beliles et al., 1980) or find only slight developmental delay (Dormueller et al., 1979). Chiu et al. (2013) cite the NRC (2006) report as verification of their risk assessment for TCE developmental toxicity, but actually the NRC (2006) concluded:

"Additional studies evaluating the lowest-observed-adverse- effect-level and mode of action for TCE-induced developmental effects are needed to determine the most appropriate species for human modeling."

"In its present assessment, the OPPT ignored the serious deficiencies already identified in conduct of the Johnson et al. (2003) rat drinking water study upon which the BMD01 was based (Kimmel et al., 2009; Watson et al., 2006)

[Attachments 1 and 2]. In their weight-of-evidence assessment, Watson et al. (2006) concluded:

'...application of Hill's causality guidelines to the collective body of data revealed no indication of a causal link between gestational TCE exposure at environmentally relevant concentrations and congenital heart defects.'

"Those conclusions were consistent with Hardin et al. (2005). Perhaps most disturbing of all in US EPA's reliance upon Johnson et al. (2003) as the key study (which for the basis for their lowest non-cancer TCE hazard index and margin of exposure) is the observation by Hardin and associates (2004):

'Conventional developmental and reproductive toxicology assays in mice, rats and rabbits consistently fail to find adverse effects of TCE on fertility or embryonic development aside from embryo- or fetotoxicity associated with maternal toxicity. Johnson and Dawson, with their collaborators, are alone in reporting that TCE is a 'specific' cardiac teratogen.'

"One of the fundamental tenants in science is the reliability and reproducibility of results of scientific investigations. In this regard, one of the most damning of the TCE developmental toxicity studies in rats is that by Fisher et al. (2005) who stated:

'The objective of this study was to orally treat pregnant CDR(CD) Sprague-Dawley rats with large bolus doses of either TCE (500 mg/kg), TCA (300 mg/kg) or DCA (300 mg/kg) once per day on days 6 through 15 of gestation to determine the effectiveness of these materials to induce cardiac defects in the fetus. All-trans-retinoic acid (RA) dissolved in soybean oil was used as a positive control.

The heart malformation incidence for fetuses in the TCE-, TCA- and DCA-treated dams did not differ from control values on a per fetus or per litter basis. The RA treatment group was significantly higher with 33% of the fetuses displaying heart defects.'

"Unfortunately, Johnson et al. (2005) failed to report the source or age of their animals, their husbandry or provide comprehensive historical control data for spontaneous cardiovascular malformations in their colony. The Johnson study with 55 control litters compared to 4 affected litters of 9 treated was apparently conducted over a prolonged period of time (perhaps years); it is possible this was due to the time required to dissect and inspect fresh rodent fetuses by a small academic research group. However, rodent background rates for malformations, anomalies and variants show temporal fluctuations (WHO, 1984) and it is not clear whether the changes reported by Johnson et al. (2005) were due to those fluctuations or to other factors. Surveys of spontaneous rates of terata in rats and other laboratory animals are common particularly in pharmaceutical and contract laboratory safety assessment (e.g., Fritz et al., 1978; Grauwiler, 1969; Palmer, 1972; Perraud, 1976). The World Health Organization (1984) advised:

> 'Control values should be collected and permanently recorded. They provide qualitative assurance of the nature of spontaneous malformations that occur in control populations. Such records also monitor the ability of the investigator to detect various subtle structural changes that occur in a variety of organ systems.'
>
> "Rates of spontaneous congenital defects in rodents can vary with temperature and housing conditions. For example, depending on the laboratory levocardia and cardiac hypertrophy occur in rats at background rates between 0.8-1.25% (Perraud, 1976). Laboratory conditions can also influence study outcome; for instance, maternal hyperthermia (as a result of ambient elevated temperature or infection) can induce congenital defects (including cardiovascular malformations) in rodents and it acts synergistically with other agents (Aoyama et al., 2002; Edwards, 1986; Zinskin and Morrissey, 2011). Thus while the anatomical observations made by Johnson et al. (2003) may be accurate, in the absence of data on maternal well-being (including body weight gain), study details (including investigator blind evaluations), laboratory conditions, positive controls and historical rates of cardiac terata in the colony it is not possible to discern the reason(s) for the unconventional protocol, the odd dose-response and marked differences between the Johnson et al. (2003) results and those of other groups.
>
> "As noted by previous investigators, the rat fetus is "clearly at risk both to parent TCE and its TCA metabolite" given sufficiently high prenatal TCE exposures that can induce neurobehavioral deficits (Fisher et al., 1999; Taylor et al., 1985), but to focus on cardiac terata limited to studies in one laboratory that have not been reproduced in other (higher dose) studies and apply the BMD01 with additional default toxicodynamic uncertainty factors appears misleading."

Rather than accepting the advice of the peer review panel, EPA relied upon an erratum published by the study authors to "reaffirm" the adequacy of this flawed and irreproducible study as the basis for the TCE Assessment. Far from reaffirming the adequacy of Johnson *et al.*, the erratum provides additional and irrefutable evidence of serious problems with that study.

Impact of TSCA Science Provisions

It is clear that a risk evaluation that supports a TSCA § 6 rule must be more robust than the screening level Work Plan assessment that EPA carried out for TCE. There can be no doubt that this is the proper characterization of the June 2014 assessment. The Chairperson of EPA's peer review panel wrote:

> "The draft document fails to articulate satisfactorily that the analysis described within should be characterized as *a screening level assessment*. . . . I believe that *the Agency acted prematurely in issuing this (screening level)* assessment for public comment. . . .

"After listening carefully to the comments and contributions from the other members of the Panel, I have concluded that there would *little benefit in revising this draft screening assessment*. Rather, I would suggest that the effort be put into a higher tier, more refined assessment which would include empirical data gathered during the course of real-world uses, e.g., as OPP regularly asks be done for occupational exposures and sometimes for residential exposures, consumer use survey data, evaluation of exposure using additional modeling tools and a revisiting and reanalysis of the choices of toxicity and epidemiologic studies used to describe the health benchmark at the MEC99 level and the rationale for selecting the singular MOE of 30 to apply to the selected studies, each of which have varying degrees of credibility. This *current draft screening level assessment* could then be attached as an appendix to the new second-generation assessment, and described, in summary form, in the early chapter(s) of the new assessment. I would have saved the resources expended for the current external peer review and spent them on the next-generation assessment."[14]

She further stated:

"By selecting the HEC99 and very conservative assumptions about exposure, one ends up with a very conservative (that is, health-protective) risk assessment, which assures only the certainty that the potential risk has not been under-estimated. It does little to resolve the uncertainty of the true estimate of risk."

The Chairperson's main point was that the information (*i.e.,* the screening level assessment) is not consistent with any intended use to support regulation. Her advice was that there would be little benefit in even revising the assessment, given its inadequacy for regulatory use. Taken together, these comments by the Chairperson of EPA's peer review panel establish quite clearly that the TCE risk evaluation does not meet the requirements of new TSCA § 26(h).[15]

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[14] https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf (emphasis added).

[15] The screening level assessment also does not comply with Office of Management and Budget ("OMB") guidelines implementing the Information Quality Act. First, EPA must conduct a "highly influential scientific assessment" to support TSCA § 6 rulemaking. OMB defines a scientific assessment as "highly influential" if dissemination of the assessment could have a potential impact of more than $500 million in any one year on either the public or private sector, or if the dissemination is novel, controversial, precedent-setting, or has significant interagency interest. The TCE assessment employed worst-case or default assumptions that led to overestimation of potential risks. Such assessments may be appropriate to support a decision that no further action or evaluation is necessary, because there is confidence that the potential risks are not a concern. However, they are inappropriate to support regulations intended to reduce risk because screening level assessments do not accurately estimate risk or quantify exposures. Second, OMB's guidelines also require agencies to subject highly influential scientific assessments to more rigorous peer review. For TCE, EPA selected a contractor to manage the peer review process, even though experts consider contractor-managed peer review to be the least rigorous level of peer review.

Moreover, as discussed above, other panelists raised serious concerns going to the heart of the "best available science" criteria in § 26(h). Peer review and public comments identified numerous scientific deficiencies with the draft TCE assessment, including the inappropriate use of default assumptions; ignoring contrary evidence that affects the weight of the scientific evidence; reliance on inapposite exposure data; conclusions inconsistent with the evidence cited; and, most importantly, reliance on a study that is not reproducible. Equally important deficiencies in both the hazard and exposure assessments were noted.

EPA completely disregarded the peer reviewers' advice and issued the final Work Plan assessment in June 2014 without making any substantial change to the draft. Under new § 26(h), however, EPA must make its science-based decisions "in a manner consistent with the best available science" and "based on the weight of the scientific evidence." In addition, EPA can no longer afford to ignore the conclusions of the peer review it initiated, as it must consider "the extent of independent verification or peer review of the information."

Finally, perhaps the most obvious problem with reliance on the 2014 assessment for rulemaking is that it would be inconsistent with new § 26(l)(4): "With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are *consistent with the scope of the completed risk assessment for the chemical substance* and consistent with other applicable requirements of section 6" (emphasis added). The assessment (p. 18) "identifies cancer risk concerns and short-term and long-term non-cancer risks for workers and occupational bystanders at small commercial degreasing facilities. . . ." It further states (p. 27): "Also, although the use of TCE as a solvent degreaser at large commercial/industrial operations is expected to be frequent and the concentration of TCE high, human exposures in these settings are expected to be monitored and controlled by Occupational Safety and Health Administration (OSHA); thus, this use is also not considered in this assessment." Finally, it states (p. 33):

> "For this risk assessment, EPA/OPPT has determined that more research will be required to determine which factors will best define small shops for the industries that do vapor degreasing. However, EPA/OPPT's interest in small shops for this assessment is due to the possibility that these shops may have fewer resources or less expertise and awareness of hazards, exposures, or controls as compared to large shops."

The SERs were told that EPA has now decided that no distinction will be drawn between large and small shops conducting vapor degreasing for purposes of the § 6 rulemaking. Such rulemaking would clearly be beyond the scope of the current assessment, however, which was limited as described above. As was clear from the comments of some of the SERs, even though they are small businesses a number of them operate large degreasing machines which were not covered by the assessment.

II. Consideration of Alternatives

The SERs were quite vocal in expressing concern about EPA's slides suggesting that n-propyl bromide (NPB), perchloroethylene, methylene chloride, and other compounds could be used as alternatives to TCE in vapor degreasing, and provided compelling technical arguments as to why they are not technically feasible alternatives. They also questioned whether these alternatives would realistically be available, given current and future planned EPA regulation of those compounds. In this regard, it is important to note that TSCA § 6(c)(2)(C), as added by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, provides:

> "(C) CONSIDERATION OF ALTERNATIVES.—
>
> "Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."

Query how compounds such as nPB could be considered a "reasonably available" substitute for TCE, much less how EPA could consider making such a finding in light of the fact that substitution on NPB in foam fabrication following reduction of the workplace limit for methylene chloride is regarded as a textbook example of "regrettable substitution." Unlike TCE, which has a long history of safe use in the workplace, the serious health impairments suffered by workers in those facilities have been widely documented.

III. Replacement Parts

A number of SERs made the point that their business consists largely of precision cleaning of parts for uses including medical, aviation, aerospace, defense, and automotive applications. Changing federal agency (*e.g.*, Food & Drug Administration for medical devices, Federal Aviation Administration for landing gear and other aircraft parts) and industry specifications for these parts takes years. Many of these parts are replacement parts. The NESHAP was careful to recognize this fact:

> "The commenters stated that many original equipment manufacturers have not approved the use of alternative degreasing solvents. The commenters also stated that changing solvents involved a rigorous approval process by the original equipment manufacturers and the Federal Aviation Administration (FAA) in order to ensure that safety and quality criteria are met. The commenters stated that such an approval process could take more than two years. . . . Two commenters associated with the aerospace industry stated that the FAA, Food and Drug Administration (FDA) and the Nuclear Regulatory Commission (NRC) guidelines

for safety and quality control often dictate the types of solvents and materials that may be used in aerospace operations. According to the commenters, solvent cleaning criteria determined the quality of adhesion between aircraft assemblies and components and the various coatings, primers, sealants, and adhesives later applied to their surfaces, and improper degreasing could cause loss of coating adhesion and ultimate failure of specific aircraft component parts. The commenters also stated that they had explored solvent alternatives such as aqueous cleaners, and had encountered incompatibilities with FAA guidelines, such as inability to meet the degree of cleaning required, incompatibility of the parts being cleaned with the cleaning solution, longer required cleaning time, and problems associated with moisture left on parts being cleaned. . . . As earlier stated, EPA is also persuaded that some solvent cleaning processes for the aerospace and narrow tubing industry are controlled by protocols from the FAA, FDA, NRC and from protocols to satisfy original equipment manufacturers' specifications. As earlier stated, EPA has also concluded in this final rule that solvent switching from PCE or TCE to MC may not be a viable option in some instances for the aerospace industry. As also explained earlier in Section III.B. of the Preamble, EPA has re-analyzed the cost assumptions made at proposal for the aerospace industry separate from the halogenated solvent cleaning machines that are covered by this final rule, and has determined that due to costs, technical feasibility, and other factors, requiring additional controls would not be feasible at this time."[16]

Equally, Congress was concerned that any § 6(a) rule not impact the supply of safe replacement parts. TSCA § 6(c)(2)(D), as added by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, includes the following requirement for any such rule:

"(D) REPLACEMENT PARTS.—

"(i) IN GENERAL.—The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

"(ii) DEFINITIONS.—In this subparagraph—

"(I) the term 'complex consumer goods' means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

[16] 72 Fed. Reg. 25,138, 25,150-152 (May 3, 2007).

"(II) the term 'complex durable goods' means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use."

This requirement is in addition to the requirement, unchanged from previous law, that "any regulatory decisions under this act undergo an implementable yet robust consideration of costs and benefits. This section requires EPA to assess the costs, benefits, and feasibility of regulatory options the Administrator has considered, and describe how that assessment influenced the choice of regulatory requirements."[17]

IV. Gap Filling Purpose of TSCA

As indicated above, TCE does not appear to present an unreasonable risk of injury to health for purposes of regulation under TSCA. Even if it were deemed to do so, however, TSCA § 9, as originally enacted and as updated by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."[18] Worker health and safety fall under the jurisdiction of the Occupational Safety and Health Administration (OSHA), and use of TCE in vapor degreasing is already more than adequately regulated under the Occupational Safety and Health Act as well as by EPA under the Claen Air Act. This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative.

OSHA Regulation

Notably, the Work Plan TCE assessment addresses potential risks to workers and bystanders as a result of its use in small vapor degreasing operations. As noted above, worker health and safety falls under the jurisdiction of OSHA, which has regulated occupational exposure to TCE for many years. The current workplace limits are 100 parts per million (ppm) as an 8-hour time-weighted average (TWA), 200 ppm as an acceptable ceiling concentration, and 300 ppm as an acceptable maximum peak (5 minutes in any 2-hour period) above the acceptable ceiling concentration for an 8-hour shift.[19] OSHA should

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[17] S. Rep. No. 114-67, at 18 (114th Cong., 1st Sess.).

[18] TSCA § 9(d).

[19] 29 CFR § 1910.1000 Table Z-2. TCE producers recommend compliance with Threshold Limit Values (TLVs) recommended by the American Conference of Governmental Industrial Hygienists. For TCE, the current TLVs are 10 ppm as an 8-hour TWA and 25 ppm as a Short Term Exposure Limit. SERs confirmed that 10 ppm is the *de facto* exposure limit.

be given an opportunity to consider whether a lower workplace standard would be appropriate. Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA's existing limits would remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the Occupational Safety and Health Act, even if the EPA regulation afforded greater protection, as long as an OSHA standard on the same substance is in effect.

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.[20] EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.*, by controlling the amount of substance used in a product or prohibiting a particular use of the substance under § 6. This is potentially much more burdensome economically than ambient standards, which permit each employer subject to the standards to achieve the necessary reduction in exposure in the most cost-effective manner. Yet TSCA § 6(c)(2) requires EPA carefully to consider the cost effectiveness of a proposed regulatory action against at least one alternative, and Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[21]

<u>EPA Regulation</u>

EPA described the requirements of the NESHAP discussed above as follows:

> "This final rule also requires owners or operators of halogenated solvent cleaning machines that use any one of the halogenated solvents covered by this rule (*i.e.*, MC, PCE or TCE), with the exception of the halogenated solvent cleaning machines used by the abovenoted industries, to ensure that facilitywide solvent emissions from all halogenated solvent cleaning activities

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[20] H. Rep. No. 94-1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act*, at 441 (1976).

[21] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

"This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

are less than or equal to the limit for the single halogenated solvent specified in Table 2 of this Preamble.

"This final rule also requires halogenated solvent cleaning machines that are constructed or reconstructed after August 17, 2006, with the exception of halogenated solvent cleaning machines associated with the above-noted industries, to comply with the 60,000 kg/yr MC equivalent emission limit upon the effective date of this rule or upon startup, whichever occurs later. The revised requirements apply in addition to the 1994 NESHAP.

"For area sources subject to the 1994 NESHAP and constructed or reconstructed after August 17, 2006, the final rule revisions add to the previous 1994 NESHAP by requiring implementation of the 60,000 kg/yr MC equivalent facility-wide emission limit upon the effective date of this rule or upon startup, whichever occurs later. This final rule also limits the use of any one of the halogenated solvents covered by this rule (*i.e.*, MC, PCE or TCE), at area sources, to the limits for the single halogenated solvent specified in Table 2 of this Preamble. The area sources in the halogenated solvent cleaning source category that are subject to GACT are not subject to these additional standards. These area sources are cold batch cleaning machines.

"When a facility's total halogenated solvent emissions from its degreasing operations exceed the applicable emission limits, the facility must implement means to comply with these amended standards. In addition, under this final rule, the 1994 NESHAP requirements for all halogenated solvent cleaning machines remain applicable. Compliance with the 60,000 kg/yr MC equivalent emission limit is demonstrated by determining the annual PCE, TCE, and MC emissions for all cleaning machines at the facility, using Equation 1 as necessary, and comparing to the emission limits in Table 2."[22]

By imposing an annual limit on TCE emissions from vapor degreasers, the NESHAP changed work practices and greatly reduced both in-facility (occupational and bystander) exposure and fenceline emissions, estimated by the SERs to be more than 95%. The NESHAP provides comprehensive regulation of this TCE application.

<u>Requirements of TSCA § 9</u>

TSCA § 9, as amended, provides:

"(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of

[22] 72 Fed. Reg. 25,138, 25,142 (May 3, 2007).

injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

> (A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
> (ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
> (B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

"(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk."

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the actions to be taken under this title and an action to be taken under such other law to protect against such risk."

If this statutory language were not sufficient to express the limitations on EPA's authority, the legislative history leaves no doubt. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[23]

Two colloquies on the floor of the House of Representatives make this intent clear with specific reference to the instant rulemaking on TCE. First:

"Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. *Blackburn*), the vice chair of the full committee.

Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.

[23] H. Rep. No. 114-176 (114^{th} Cong., 1^{st} Sess.) at 28.

Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).

It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.

Would the chairman please confirm my understanding of section 9?

Mr. SHIMKUS. Will the gentlewoman yield?

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work."[24]

Second:

"Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

[24] 162 Cong. Rec. H3028 (May 24, 2016).

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:

Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and that authority sufficiently protects against a risk of injury to human health or the environment; or

Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.

Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue."[25]

Indeed, TSCA § 9 was strengthened by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and it was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance Act not be used, when another act is sufficient to regulate a particular risk."[26] EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the Occupational Safety and Health Act, and referring the matter for action by OSHA.[27] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that "Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[28]

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[25] *Id.*

[26] 122 Cong. Rec. H11344 (Sept. 28, 1976).

[27] 50 Fed. Reg. 27674 (July 5, 1985).

[28] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

There is no evidence that EPA has submitted to OSHA "a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk," as required by TSCA § 9(a)(1). The non-existent report obviously did not "include a detailed statement of the information on which it is based" and was not "published in the Federal Register," as required.

Had the required report been issued, it presumably would have identified how OSHA's authority over the workplace was insufficient to address the risks posed by vapor degreasers using TCE. A letter from the Assistant Secretary of Labor for Occupational Safety and Health (undated but apparently issued on April 4, 2016) identifying limits on OSHA's authority to regulate hazardous substances such as TCE was provided to the SERs. This letter does not come close to meeting the requirements of TSCA for EPA action in this case. The April 2016 letter identifies no such gap specific to vapor degreasing in any particular category of work place, rather it simply recites how OSHA's authority does not extend to self-employed workers, military personnel, and consumer uses. But those are limitations that were imposed by Congress and have existed since the Occupational Safety and Health Act was enacted. Those limitations apply to every use of every toxic substance. Congress cannot have meant, in enacting "gap-filling" legislation, to open the door to EPA assuming all authority over the use of hazardous substances in the workplace.

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[29] It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

Finally, EPA has not taken into account its own extensive regulation of vapor degreasing under the Clean Air Act. The NESHAP referenced above applies to all vapor degreasers at major sources, except solvent cleaning machines used in the manufacture and maintenance of aerospace products or narrow tubing, and continuous web cleaning machines, as well as all vapor degreasers at area sources.[30] This

[29] As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

[30] *See* 40 C.F.R. § 63.460(i).

extensive regulation precludes regulation under TSCA § 6 unless EPA can make a determination under TSCA § 9(b) "that it is in the public interest to protect against such risk by actions taken under this Act." Such a determination would not seem reasonable where sponsors of the Frank R. Lautenberg Chemical Safety for the 21st Century Act have stated the view that EPA's "own existing regulatory framework already appropriately addresses risk to human health" for TCE in vapor degreasing.[31]

[31] 162 Cong. Rec. H3028 (May 24, 2016).

8. Precision Machined Products Association, Miles Free, Director, Industry Research and Technology, from Brecksville, OH

PMPA PRECISION MACHINED PRODUCTS ASSOCIATION

Helping Precision Machine Shops Be More Productive and Profitable

15 June 2016

Nathaniel Jutras
U.S. Environmental Protection Agency
Regulatory Management Division

Re: Trichloroethylene Small Business Advocacy Review Panel Comments from PMPA

Dear Nathaniel:

PMPA is pleased to have been able to participate via web conference in the June 15, 2016 Small Business Advocacy and Review Panel to help EPA gain additional facts regarding the essential nature of TCE as a vapor degreaser for critical products manufactured by our small business member companies in the precision machining industry. We also appreciated the opportunity to share some issues of concern as well to our small manufacturing businesses. Thank you for considering our verbal and written comments as you consider the regulatory approach to TCE.

Questions of Reasonable Risk

Frankly, our first concern is of what constitutes "authoritative science" when looking at the potential impact of the regulations built on "Baseline Risk Estimates"- that claim authority at fractions of a part per billion level - while the National Academies of Science - when reviewing actual data from exposures resulting from TCE contamination at Camp Lejeune - were unable to find "Sufficient Evidence of a Causal Relationship," or "Sufficient Evidence of an Association." The National Academies' report found "Limited / Suggestive Evidence of an Association" for PCE or Solvent Mixtures, in 14 health outcomes, and found "Inadequate / Insufficient Evidence to Determine Whether an Association Exists on 44 Health Outcomes - only 4 of which were characterized as potentially thought to be connected to TCE.

It is hard for us to understand how EPA analysis can be so certain in its condemnation of TCE while the National Academies, working with actual exposure data was unable to find evidence of even a causal relationship. That our small manufacturing businesses should face existential impacts as a result of a regulation on TCE when the National Academies were unable to find a causal relationship for negative health outcomes while the EPA can confidently determine risk to a fraction of a part per billion is unfounded, ill-considered, unjust, and calls loudly for a referee of the actual risks. "No Evidence of a Causal Relationship" cannot be simultaneously held to be true with "AEL cancer 8hr TWA= 0.4ppb." We are not sure how these mutually exclusive declarations can coexist, nor how regulatory policies can be held to be valid given the divergence of these values and the authorities claimed.

Link to National Academies report: http://www.nationalacademies.org/includes/clfinal.pdf

Substitute Chemicals- Impropriety of EPA offering 1-bromopropane (n-Propyl Bromide (nPB)) as a "Drop-in Substitute" for TCE

Frankly, we were shocked to find nPB offered by EPA as a drop in substitute for TCE, given the wide knowledge of nPB neurological damage resulting from workplace exposures. (EPA Slide 32)

We'll let the New York Times reporting on nPB from March 30, 2013 stand in for our comments on this. The prescription of nPB as a "drop-in substitute" for TCE by EPA seems to be misfeasance at best.

> "Medical researchers, government officials and even chemical companies that once manufactured nPB have warned for over a decade that it causes neurological damage and infertility when inhaled at low levels over long periods, but its use has grown 15-fold in the past six years."
>
> "But the story of the rise of nPB …is a parable about the law of unintended consequences. "
>
> "It shows how an Environmental Protection Agency program meant to prevent the use of harmful chemicals fostered the proliferation of one, and how a hard-fought victory by OSHA in controlling one source of deadly fumes led workers to be exposed to something worse — a phenomenon familiar enough to be lamented in government parlance as "regrettable substitution.""
>
> Link to NY times Story on NPB: http://www.nytimes.com/2013/03/31/us/osha-emphasizes-safety-health-risks-fester.html?pagewanted=all&_r=1

As manufacturers committed to having safe and compliant workplaces and to protecting the health and lives of our employees, we must ask if anyone at EPA did any kind of risk analysis before pasting "1-bromopropane" into the slide for this SBAR Panel as a *"drop-in substitute for TCE." (Note, on slide 7 of the same EPA presentation EPA states that "Draft Risk assessment for 1-bromopropane released for public comment and peer review- Draft risk assessment found cancer and non-cancer risks (developmental toxicity, reproductive toxicity, and neurotoxicity) for occupational users and bystanders to degreasing and other uses.") How can EPA prescribe nPB as a "drop-in replacement" for TCE knowing these risks?*

We would ask why, and on what basis, EPA suggests that we replace an undocumented hazard (TCE-National Academies) with a demonstrated one (nPB- NYTIMES). Surely EPA understands its authority and implied credibility in these matters; how are we to take fraction of parts per billion estimates of risk seriously when EPA suggests nPB as a "drop-in replacement" despite demonstrated and widely reported workplace epidemiological consequences? The provision of the list of "drop-in substitutes" seriously damages the credibility of EPA in this area, especially given EPA's admission of hazards for nPB on slide 7.

<u>Concerns That Risk Data and Assumptions Do Not Reflect Current Industry Processes</u>

We were surprised to learn that the working definition of "open top degreasing" in use by EPA officials at the meeting on the call meant to them "not under a vacuum." PMPA provided, and was supported by other small business representatives on the call, that typical processes for the use of TCE for vapor degreasing in our precision machining industry are "enclosed systems with vertical conveyor pass-through's, super-heated vapor zone to prevent vapor from rising out, operator loading station outside of enclosure, ventilation and air scrubbers. All operating in compliance with EPA permit, and best practices for worker safety including Engineering Controls, Personal Protective Equipment (face mask and elbow length gloves) and Worker Training." That EPA could consider such a typical operating system to be synonymous with "open top degreasing" begs the question of just what assumptions are at the basis of the proposed rule – outright ban or SCBA PPE. We remain skeptical that the authors of the proposal have a genuine understanding of the process, and are thus basing their thinking on conditions that are certainly not typical in our small business, precision machining, manufacturing shops today.

<u>How TCE Is Used in Our Shops</u>

PMPA sent a request for information to approximately 240 PMPA active member shops regarding TCE and vapor degreasing. About 5% or 12 shops responded and have provided the information which we aggregated and used as the basis for our comments on the call, and in these written follow up comments. An additional handful (4) of these shops responded to my request for a deeper dive on their processes, practices, consumption, etc.

Typically, annual usage was reported to be in the hundreds of gallons range- 291, 110, and 145 gallons reported by three shops, one shop used ~2000 gallons last year.

All shops reported running 8 hours per day- 240-250 days per year.

Typical systems reported for TCE in our precision machining industry are "enclosed systems with vertical conveyor pass-through's, super- heated vapor zone to prevent vapor from rising out, operator loading station outside of enclosure, ventilation and air scrubbers. All operating in compliance with EPA permit, and Best practices for worker safety including Engineering Controls, Personal Protective Equipment (face mask and elbow length gloves), and Worker Training."

Typically, 100% of shop production is cleaned in the TCE vapor degreaser unit at these shops. One shop uses TCE only for critical items with blind holes, rigorous cleanliness requirements, and critical metal to glass seal components. Shops mentioned "Frozen practices" for automotive, defense and other customers which we will discuss further below.

Commercial, Contract, & Technical Issues If TCE Prohibited as Reported by PMPA Shops Using TCE

- Where TCE is used it is the sole means of parts cleaning-100% of shop output affected
- No comparable cleanliness using alternative methods systems has been found by shops that have been investigating alternatives. This was reported to us by several respondents.
- TCE is favored for degreasing machined metallic inserts to be used in conjunction with a number of plastics / polymers / engineered materials, as it is said to not attack them.
- Several shops have reported to me that they had replaced TCE and would no longer be participating in our ad hoc process addressing the EPA's TCE proposed rule for TCE. They have not said that they were at the same level of productivity nor cleanliness and intimated that they were struggling to get there, but they "did what they thought that they had to do."
- Failure to completely remove oil can affect the reliability of the automatic optical and electronic gaging systems in place to assure 100% verification on human safety critical automotive and aerospace parts.
- Companies that we spoke with stated that Aerospace, Defense, Medical and Automotive contracts locked in their cleaning methods as part of the approval process. ***Many end use customers demand that the critical machined parts that our shops supply be free from oil.***
- Compatibility of replacement cleaners is an issue as TCE is accepted for its compatibility and non- attack of polymers. This is especially important in defense applications, and for inserts to be molded into plastic.
- One shop (65% automotive) making airbag, braking, and other engine mount parts ***estimated that the re-approval process for a new cleaning process with their automotive customers would entail between 5 and 10 man- years of engineering level talent to do actual testing, document results, prepare automotive FMEA/PPAP documentation, submit, and then follow up with customers for approval.***
- It was noted that many shops in Europe have been exempted from any ban on TCE there due to requirements by BAE, Airbus, and others for parts to be TCE cleaned to assure polymer compatibility and oil free as received. If this is true, the proposed rule would effectively prohibit U.S. precision machining shops from supplying parts to these companies.
- One respondent noted that their orders which mandated the use of TCE in their process came from Defense Supply Logistics center in Philadelphia. Other customer companies mentioned by our respondents included Raytheon, Command, Curtiss Wright, and Electric Boat that purchase critical components that could be affected by the proposed rule.

- One respondent noted that TCE was essential in the parts that they make for metal to glass sealing and electronic connectors applications. Presence of any soil or contaminant material at all prevents the creation of the uniform oxide film needed on the metal part to assure glass adhesion. Here's what they said, "*we incorporate engineering controls to meet or exceed EPA air emissions standards and have found no better method or cleaning fluid to ensure a glass to metal seal that will meet or exceed military or commercial specifications.*"

Small Business Potential Impacts of Prohibition of TCE

- Cost estimates to replace cleaning equipment ran from $350,000- to $500,000. (Most shops would have to finance purchases this large, adding cost of borrowed capital.)
- One shop that just made the switch from TCE to another method has invested over $500,000 in equipment and workplace modifications.
- These estimates ranged from 25% of net revenue to total annual profit in some of the shops consulted.
- The expenditure of $350,000 to $500,000 is equivalent to 2-3 years of planned capital investments and would leave our shops that far behind competitors in South Korea, China, Indonesia, Malaysia and India who are investing in new technologies and capabilities.
- This level of expenditure would starve our shops from capital to upgrade their current processes, purchase new equipment, and make needed improvements, putting them 2-3 years behind market competitors.
- None of the shops had estimates of costs of transition that included customer rejections and rework related to change in quality of as received parts as a consequence of the transition.
- Smaller companies (12-75 employees) felt that a mandate to replace cleaning equipment that required $350,000 or more would be a tipping point decision regarding closing or maintaining the business.
- Shop closings would put all employees out of work at these shops (roughly from 12-70 employees per shop in our sample of companies).
- Shop closings would destroy millions in owner's equity as the business assets would be sold for liquidation value only.
- One shop said that at $500,000 cost for new cleaning technology would consume their total planned 5-year capital investment budget.
- Several of our shops said that a prohibition was likely to force them to close if replacement technology costs ran as estimated.
- Replacement fluids for TCE were quoted at 10X the price of TCE. *(Kyzen M6900 was mentioned as a possible replacement by one respondent, we noted that this product is not even shown on the Kyzen website…?)*

Final Thoughts On Small Business Impacts

Our comments today and in this document are based on actual PMPA member company provided information. As mentioned earlier, our query determined that 5% of 240 PMPA companies had TCE process involvement when we first learned of this proposal. If you were to extrapolate PMPA membership to the entire industry (NAICS 332721 - Precision Machining) that 5% number would be times 3,559 establishments, so possibly impacting 178 shops. At the industry average of $5,000,000 in sales, we would expect those shops to employ 5,394 employees (using $165,000 in sales per employee to determine employee census). The lost sales from those 178 shops would be just short of $1 billion, at $890,000,000. (The Total Value of Shipments for the U.S. precision machining industry was reported to be $18.5 billion in 2014.)

The National Academies of Science could not find a causal relationship between TCE and a large number of health outcomes, yet the EPA is proposing a rule likely to shut down as many as 178 precision machining shops nationwide, eliminating potentially over 5,000 jobs (in just our precision machining industry), while reducing U.S. Manufacturing GDP by almost a billion dollars. This will be repeated in many sub - industries across Fabricated Metals Sector as well as those noted on EPA slide 26 - Instruments and Related Products, Machinery, Electrical and Electronic Equipment and Miscellaneous manufacturing industries where TCE is also used as a vapor degreaser here in the United States.

Despite the National Academies' findings, EPA claims risk certainty to 0.4 of a part per billion of exposure, and is willing to wager the livelihood of 5000 machinists, the potential shutdown of almost 200 small manufacturers, and loss of almost $1 billion in manufacturing GDP, while suggesting that nPB and PCE are according to US EPA, "drop-in substitutes."

We find much to be confused about in this proposal starting with EPA's certainty about TCE exposure limits to the parts per billion level despite no apparent epidemiological confirmation of the etiology in workers in affected industries, and contrary findings by the National Academies of Science. We remain concerned that EPA's assumptions regarding our processes, "open top means not under a vacuum" have EPA rule makers designing solutions for problems that no longer exist. We share our concern as small business entities (according to U.S. Census the average NAICS 332721 shop has $5 million in sales) that as many as 5% of our industry could be forced out of business by the costs of compliance for the proposed rule. This is aggravated by our substantial doubts as to the credibility of EPA's risk estimates in light of the National Academies' own report on TCE and actual health outcomes in 2011. Finally, we question the standard of care used by EPA to prepare this rule, noting several flaws in the assumptions used and in the prescribed "drop-in substitutes" mentioned multiple times by EPA in their presentation.

PMPA respectfully requests that EPA reassess its assumptions regarding exposure limits, its assumptions regarding processes and exposures currently found in the industry, and its insistence that there exists a toxic connection between TCE and various cancer and non-cancer health outcomes for which the National Academies found "no causal relationship nor any associated relationship."

We respectfully suggest that EPA delay any further work on this proposed rule until we have clarity on the version of TSCA that passed the House and Senate and that will become the law of the land upon signature by the president.

We respectfully request that EPA drop its faulty and fictional notion that there exist "drop in replacements" for TCE. TCE remains an unmatched cleaner that is critical to many US high technology and advanced technology manufacturing applications. Critical modern transportation, safety, communications, computing, and defense applications require the unmatched performance provided by TCE.

Sincerely,

Miles Free
Director, Industry Research and Technology
Precision Machined Products Association

MF:mk

9. E. C. Styberg Engineering Company, from Racine, WI

Mr. Jutras,

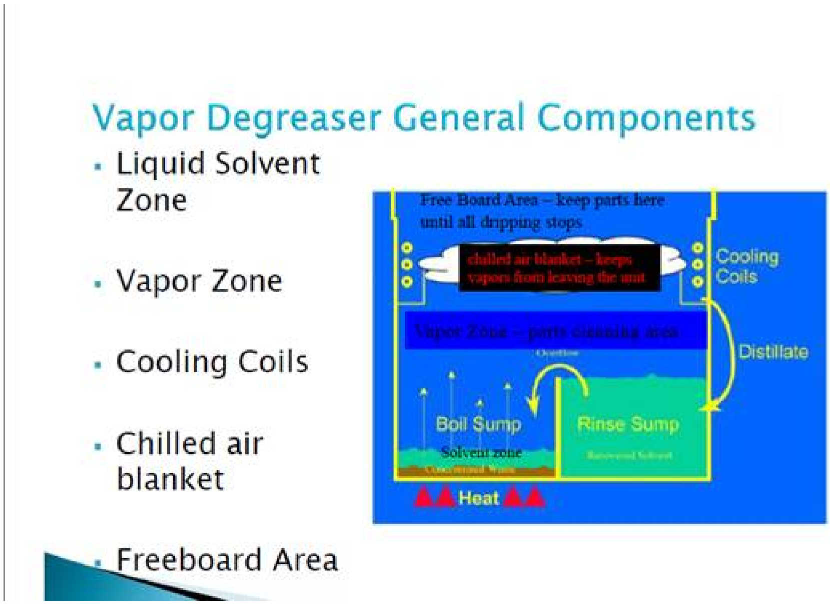
Please reference my following answers as they are organized by the number and letter layout of the original questions:

1)
a. 150
b. 1
c. "Near" is a relative term, but the minimum distance for an occasionally passing forklift driver (3-4 times per hour) is 15 ft from the lip of the free board area of the open top degreaser. The closest stationary worker, also separated by a wall between their position and the degreaser, is about 50 feet away.

2) Based on 2016 internal labor reports (1/01/16 to 6/28/16)
a. 3.5 days per month
b. 1.3 hours per operating day
c. 1.3 hours per operating day

3)
a. Title V air permit shows installation date of March 1977 (39 years old); no other paperwork found to corroborate that date. Electrical schematic found with date of 2/28/1979 but do not know if schematic was issued pre or post installation.
i. A refrigerated cooling coil was added for redundancy purposes pre-1998, complementing the original non-contact cooling water coil (which acts to condense the TCE) and the original refrigerated coil that prevents any excited non-condensed vapor from exiting the open interface of the degreaser. The upgrade occurred pre-NESHAP reporting so there was no paper record kept of cooling coil upgrade.
ii. There are no upgrades planned since the system is operating efficiently and is complying with the federal and state halogenated solvent cleaning machine MACT standards and the 'Alternative Standard'.
b. The system Styberg uses is an Autronics Model #603030 Open Top Batch Vapor Degreaser equipped with a Model #90 E still.
The original operation manual or any machine schematics, other than an electrical schematic with a date of 2/28/1979 could not be found. Styberg does have written maintenance and operating procedures for the machine and control devices in place. The following is the diagram that our company uses during annual training to illustrate how the degreasing system works. The biggest difference between the unit in the picture and Styberg's setup is that we use a connected still (separate unit) to process the condensed solvent waste instead of allowing the waste to aggregate on the degreaser's boil sump bottom. The still takes the particulate/oil laden TCE condensate from the rinse sump, purifies it through distillation and returns it to the boil sump in the degreaser for further heating to vapor. The still is completely enclosed and is a slave to the open top degreaser unit. The diagram below also shows the 3 sets of cooling coils that trap the heated TCE vapor under a chilled air blanket that the coils create (bottom coil = non-contact cooling water (NCCW), middle coil = chemical refrigerant, top coil = chemical refrigerant). The chilled air blanket must be kept at or below 56.7 degrees Fahrenheit which is 30% of the TCE's boiling point; the blanket keeps the vapors from leaving the unit. During the degreaser's working mode, all coils are kept active. Parts can either be cleaned purely through vapor action or sprayed with the liquid TCE that is taken from the still returned boil sump bottom. When the degreaser is idle, only one of the two refrigerated coils are active and the NCCW coil is always left on. Preventative maintenance is performed on the degreaser annually; the refrigerant in the coils is recharged during the

PM to make sure that the temperature of the chilled air blanket can be maintained under the 56.7 deg F threshold indefinitely.



c.
i. N/A
ii + iv + v. Styberg conducts annual vapor degreaser training for all degreaser operators with the objective of keeping the solvent vapors from reaching the atmosphere. The side benefit of that training is that they are concurrently keeping the vapor from reaching their lungs or skin in the process. Whatever fugitive vapor that is emitted beyond the chilled air blanket eventually makes its way to an exhaust fan in an adjacent room. The operators are instructed to always keep the two halves of the guillotine style accordion cover closed unless parts are being lowered into the vapor zone of the degreaser or cleaned parts are being removed and allowed to drip liquid TCE back into the degreaser from the free board area. When using the spray wand to clean parts, the operator is told to keep the cover as closed as possible with end of the sprayer wand in the vapor zone. The hoist is programmed to not exceed 11 feet per minute when lowering or raising parts out of the degreaser so that the vapor is not agitated out of the vapor zone (beyond the chilled air blanket). There are also plastic curtain enclosures around the immediate degreaser area to reduce any drafts from adjacent rooms. The measured air speed within 6 inches of the top of the free board area is not allowed to exceed 50 feet per minute at any time. No fans or any air disturbance are allowed within the curtained area of the degreaser. Both the hoist speed and draft wind speed are measured and recorded quarterly. The chilled air blanket has its temperature probed and recorded weekly. Styberg has never encountered an exceedence in any of these areas of concern. Lastly, there is an emergency stop button in an adjacent room that the operator can press if any signs of malfunction are present with the degreaser. It shuts off all electrical power to the degreaser and still with the exception of the refrigerant coils and NCCW coil. No worker spends more than 4 hours per day operating the degreaser at a time.
iii. Safety glasses with side shields, nitrile elbow length gloves and protective apron. No respirators are worn.
d. The only practice to alleviate exposure is to limit the time to 4 hours per day for any worker to operate the degreaser. The three cooling coils are intended to serve as a barrier to any OSHA threshold

amount of TCE vapor emitted during working mode. No testing of the atmosphere has been performed to my knowledge to determine actual airborne concentration versus proximity to degreaser.

4)
a. No. See answer to 3d.
b. N/A

Please let me know if an external/internal picture of the degreaser or external picture of the connected still would aid in the EPA's analysis of worker exposure.

Thank you for your time in going over this information.

Viking Drill and Tool, Inc.
355 State St.
St. Paul, MN 55107

TSCA Section 6 Proposed Rule: TCE in Vapor Degreasing
Panel Outreach SER Questions for Discussion
6/15/2016 Meeting 10:00 - 12:30

For all vapor degreasers:

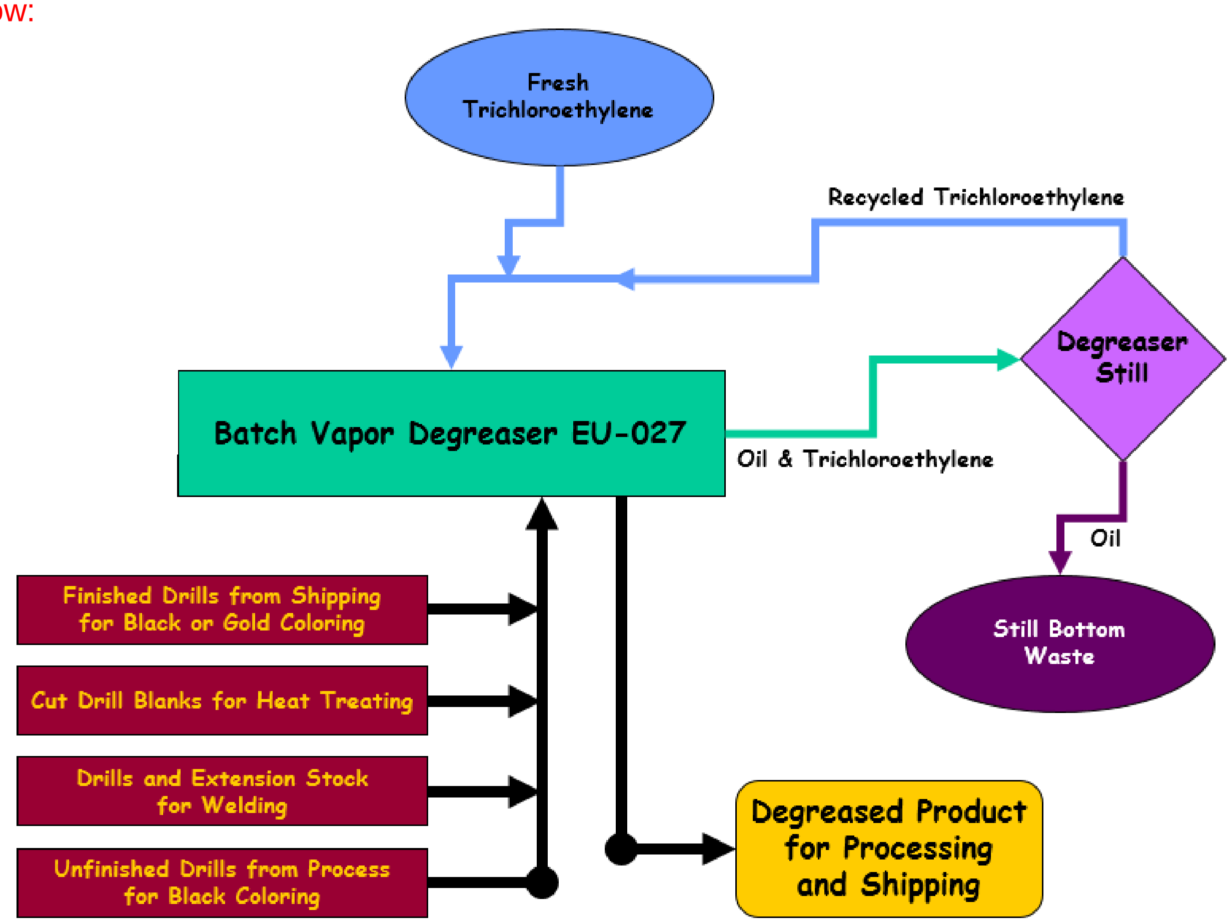
1) Your business:

a. What items do you degrease with vapor degreasing?

Work in process and finish drills have to be degreased.

b. What type of system do you use (open-top, closed, closed with vacuum, etc)? Can you provide a brief description of your system and how it works?

Viking Drill and Tool uses the closed system with exhaust degreaser. See Diagram for process flow:



c. What size system do you use?

750 gallons

d. How significant is vapor degreasing to your business overall?

Degreasing is required for all drills and taps. Without TCE vapor degreasing, we will not be able to Blacken or Golden product. More than 90% of products are Black or Gold.

e. Do any particular items or soils present special challenges?
Water presents a challenge to the drills because it leaves stain and rusts drills.

2) Current work practices related to vapor degreasing:

a. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?

Solvent capacity: 750 gallons degreaser + 185 still

b. Do the types of vapor degreasers we are considering (open-top, enclosed vacuum, continuous strip, and inline belt vapor degreasers) seem representative of those currently in use for small businesses?

No. We currently have an enclosed system with exhaust.

c. How many hours per day do you operate your vapor degreaser? How many days per year? Is there any difference for the different types of vapor degreasers?

24 hours/day, 5 days/week and ~10% overtime

d. Regarding the operation of various degreasing systems in small businesses, do you think the following is a reasonable range of solvent use?

i. Between 452 and 1,120 gallons of TCE per year for all open-top vapor degreasing units

ii. Average annual use of 1,500-1,600 gallons per year for conveyorized vapor degreasing units
iii. Average annual use of 400-500 gallons per year for enclosed vacuum vapor degreasing units

Closed system with exhaust: 350 gallons per year.

e. When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc)? What prompted this update?

February 2003, new degreaser installed because we were over capacity with the system we had due to increased work flow.
March 2015, installed a new recycler (Still) to increase workflow and extend life of TCE.

March 2016, replaced ventilation system for the still and degreaser operation

f. How large is your facility that uses vapor degreaser? (ie., dimensions of the room that the degreaser units is used and overall size of facility)

Degreaser: ~26’ x 5’ x 12’

Facility: ~80,0000 FT2

g. How many employees perform degreasing operations? How frequently?
2 employees per shift for 3 shifts

h. How many employees are located in the same room with the degreaser unit but not necessarily operating the machine?

i. What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?

6 employees over 3 shifts

3) Using TCE in your business:

SBAR Panel Discussion Questions: TCE in Vapor Degreasing

a. If TCE were not available for degreasing, how would you adjust and what would the impacts be on your business?

Option 1: n-Propyl Bromide but it will cost ~2x the price of TCE

Option 2: CO_2 Technology but equipment will cost about $0.5 Million.

b. What are your current and best practices to protect workers from exposure to TCE? For example, do you or your colleagues use ventilation or engineering controls, personal protective equipment, worker training, or other methods?

Eng. Control on Degreaser: Closed degreaser with exhaust, Super heater, and cold trap
PPE: Supplied Air hoods and chemical suites and other PPE
Worker Training

c. What are the benefits to your business of TCE?

TCE Benefits: clean cosmetic finish on products, can provide a broader color combination of drills which is more desirable and able to increase sales.

4) Exposure reduction for vapor degreasing
a. What are your experiences with:

i. Installing or updating ventilation and local exhaust

ii. Installing or operating other engineering controls

iii. Equipment changes to reduce exposures

iv. Monitoring worker exposures to chemicals in the air
Test result: 2/2016 = 0.40 ppm for 8 hour TWA

v. Air-supplied respirators: Yes

vi. Other personal protective equipment
Chemical suits, gloves, boots,

b. If you have changed or updated your exposure reduction technology or methods, how long did that process take?
n/a

c. What do you do to comply with OSHA standards for TCE?

Eng. Control: closed seal degreaser = exposure of 0.40 ppm per 8 hr TWA

Initial and Annual training: NESHAP, Right To Know, Hazardous Material handling,

Dedicated exhaust system

More efficient still reduces exposure as a result of less hazardous waste being generated.

5) Substitutes and alternatives:

a. How do you know which chemicals are in the products you are using?

Information from SDS and/or chemical manufacturer

b. What are the trusted sources of information for you about chemicals you use?
Information from SDS and/or chemical manufacturer

c. Have you tried using alternative chemicals or methods for degreasing? What were the results?

The company has tried n-Propyl Bromide but it will cost ~2x the price of TCE.

i. Please discuss alternative methods to vapor degreasing as well as alternative solvents or equipment in your vapor degreasing process

ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?

Process stays the same but need different chemical.

iii. If you have tried or switched to alternative chemicals or methods, how long did that process take? Did it require equipment modifications or new equipment purchases?

If the Viking Drill and Tool used CO_2 to clean then will need to install equipment.

d. If TCE could no longer be used for vapor degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?

e. If TCE could no longer be used for vapor degreasing and you were to choose another solvent, would you have to make specific changes to your system to meet emission requirements?

Drain, decontaminate the system, and fill machine. (~$80k)

i. What would those changes be?

Drain, decontaminate system, fill machine, dispose. (~$80k)

ii. What would it cost to make those changes in order to be compliant with emissions requirements? [Please note that these would be the changes associated with meeting emission requirements and not those associated with converting or otherwise updating systems to operate using the new solvent.]

6) Regulatory options

a. Which of the regulatory options presented today would you recommend?

b. Cost estimates: In your experience, are the cost estimates reasonably representative for both options presented?

SBAR Panel Discussion Questions: TCE in Vapor Degreasing
c. Can you think of ways to add flexibility to this rulemaking for your small businesses?

d. How do you learn about EPA regulations and what you should do to comply?
EPA contact me

e. What is the best way to reach out to members of your industry?

Contact information:
7) Nathaniel Jutras, RFA/SBREFA staff contact
EPA Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov

11. Whittet-Higgins Company, Andrew A.O. Brown, from Central Falls, RI

whittet-higgins company

33 HIGGINSON AVENUE CENTRAL FALLS, RHODE ISLAND 02863
TELEPHONE: 401 728-0700 FAX: 401 728-0703 WWW.WHITTET-HIGGINS.COM

Mr. Nathaniel Juntras
U.S. Environmental Protection Agency
Regulatory Management Division
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

30th June, 2016

SUBJECT: Small Business Entity Response to TCE Rulemaking

Dear Mr. Juntras,

We thank you for inviting our company to participate in the TCE Vapor Degreasing rulemaking outreach meeting.

Whittet-Higgins Company is an industrial engineering, automation, and manufacturing company based in Central Falls, Rhode Island. Our staff of just over forty (40) employees focuses on manufacturing precision, internally threaded retaining components for the world of mechanical power transmission. Whittet-Higgins designs, engineers, and manufactures components for a diverse clientele including aeronautical, defense, national research laboratories, and capital equipment manufacturers throughout the world. *Whittet-Higgins is the last domestic manufacturer of these components in the United States.*

Our staff of manufacturing engineers, mechanical engineers, and physicists has reviewed the EPA's Work Plan Chemical Risk Assessment for Trichloroethylene of June 2014 and the EPA's Power-Point Presentation for the Rulemaking under TSCA for Use of Trichloroethylene of March 17th 2016. Our engineers question: (1) The accuracy and validity of the estimates and assumptions made by the authors of these reports based upon our industry experience and knowledge (2) The safety benefits of the "drop-in" and "non-drop-in" substitutes that the authors reference and (3) The practicality of the EPA policy forcing manufacturers to spend hundreds of thousands of dollars replacing existing safe and functional equipment with alternative cleaning equipment and solvents.

(1) *Background*: Our experience with solvent cleaning systems that utilize Trichloroethylene shows a drastically different exposure scenario to that described by the EPA's risk assessment. Whittet-Higgins Company installed its existing Trichloroethylene Solvent Cleaning system in August of 1997. Our company chose to invest in a fully automated system to improve productivity of its workforce, improve repeatability of its product cleaning and preservation, and protect its employees from being exposed to harmful chemicals. Our automated system eliminates the need for an employee to be exposed to trichloroethylene during the cleaning process. The operator is routinely within twenty-five (25) feet of the cleaning system, and is the closest employee at any given time. Several other employees are within seventy-five (75) feet of the system

Degreasing System Layout and Operation: Our system, manufactured by Greco Cleaning Systems of Providence, Rhode Island, consists of the following components: Walking beam loading station, Double tank vapor degreasing chamber, Preservation oil dipping tank, Walking beam unloading station, and PLC Controlled Gantry loading & unloading robot. Attached to this letter in Exhibit 1.1 – Overview of Greco Degreasing System are several pictures of our system.

The main component in the system is the double tank degreasing chamber that is a partially open-top system. The double degreasing chamber was manufactured with a pneumatically actuated sealing cover that closes the chamber and when the machine is not in use and cleaning parts. The opening and closing of the cover is actuated by the PLC (programmable logic control) and only the gantry loading robot comes in contact with the degreasing chamber. The main degreasing chamber was manufactured with three (3) condensing coil chiller zones to eliminate trichloroethylene vapor escaping the system during the cleaning process. When the system is not in use, the Trichloroethylene vapor produced from the system is exhausted out of our facility to eliminate employee exposure.

Since the manufacture and installation of the system in August 1997, Whittet-Higgins made the six figure investment in September of 2006 to replace the machine control and robot actuators. The referenced figures from Exhibit 1.2 – Whittet-Higgins Degreasing System Operating Data have been taken from the new control's lifetime workpiece counts and total operation times.

Daily Exposure: In the last one-hundred and seventeen (117) months of machine operation we have found that between the two (2) shifts that our facility is open each day, our degreasing system operates less than nineteen (19) minutes per day. Furthermore, during those nineteen (19) minutes, our employees are never directly exposed to the Trichloroethylene fumes due to the automation in place. Only the robot is directly exposed to the fumes. The tank openings are above the operator's head, and as the fumes are lighter than air, the fumes move towards the ceiling where they are then exhausted outside of the building, never passing directly by the operator. ***The EPA's assumption that a person will operate a Trichloroethylene degreasing machine and be exposed to vapors for eight (8) hours a day with modern machinery and safety measures is statistically inaccurate.***

Life Time Exposure: The United States Bureau of Statistics has calculated that the average worker stays at a company less than 4.4 years. Since upgrading our degreasing system in September of 2006, the turn-over of Whittet-Higgins material handlers that load and unload our degreasing system has been above the average provided by the United States Bureau of Statistics. Whittet-Higgins has had seven (7) different material handlers loading our system, with an average stay with our company of just over twelve (12) months. Material handling is typically the lowest paid positions within progressive companies, and routinely sees excessive turnover rates. ***The EPA's assumption that a person will operate a Trichloroethylene degreasing machine for forty (40) years is again statistically inaccurate.***

(2) Our staff has investigated the substitutes, as presented in EPA's Power-Point Presentation for the Rulemaking under TSCA for Use of Trichloroethylene of March 17th 2016, for toxicity and ability to clean.

Methylene chloride (Dichloromethane) solvent has toxicity similar to Trichloroethylene and is subject to the same permissible exposure limit.

Perchloroethylene (Tetrachloroethene) is highly toxic, carries similar health risks for direct exposure, has been banned for use in the state of California, and has a lower worker exposure limit than Trichloroethylene.

1-Bromopropane (n-propylbromide) carries greater health risks than Trichloroethylene, has a lower exposure limit than Trichloroethylene, is under current review by the EPA, and has been found to be so toxic that California's Occupational Safety and Health Administration set the permissible exposure limit at 5 ppm.

Hydrofluorocarbon solvents (1,1-dichloro-1-difluoroethane; 1,1,2-difluoro-1,2dichloroethane; 1,1,2,2,3-pentafluoro-1,3-dichloropropane) poses identical health risks to the solvents above.

Hydrofluoroethers solvents are typically manufactured with a base ether and (methyl nonafluoroisobutyl ether; methyl nonafluorobutyl ether; ethyl perfluoroisobutyl ether; ethyl perfluorobutyl ether) and mixed with a trans-1,2-dichloroethylene (t-DCE) for cleaning. All are toxic to humans.

Hydroflouroolefin (2,3,3,3-Tetrafluoropropene) which is typically used in the manufacture of newest generation of refrigerants and by Honeywell Corporation in its line of Solstice PF Brand cleaning products. This product requires a positive pressure air supplied respirator when in use.

The "Drop-in" and Non-Drop-in" solvent alternatives as provided by the authors are as dangerous, if not more, than Trichloroethylene and provide no increase in worker safety.

(3) Our staff has analyzed the non-drop in alternatives and found the only alternative solvent that provides us the level of cleaning required by our customers, meets the department of Defense MIL-P-116J standard, and does not chemically damage our products are modified alcohol cleaning solvents. We have investigated several companies that manufacture explosion proof cleaning systems with automation that are compatible with modified alcohols and are aware that an investment of approximately $650,000 would be required to replace our entire existing automated vapor degreasing system. We question the logic of requiring a small manufacturer such as Whittet-Higgins to bear such a cost without the EPA providing a direct financial subsidy to help offset these policy-change induced costs.

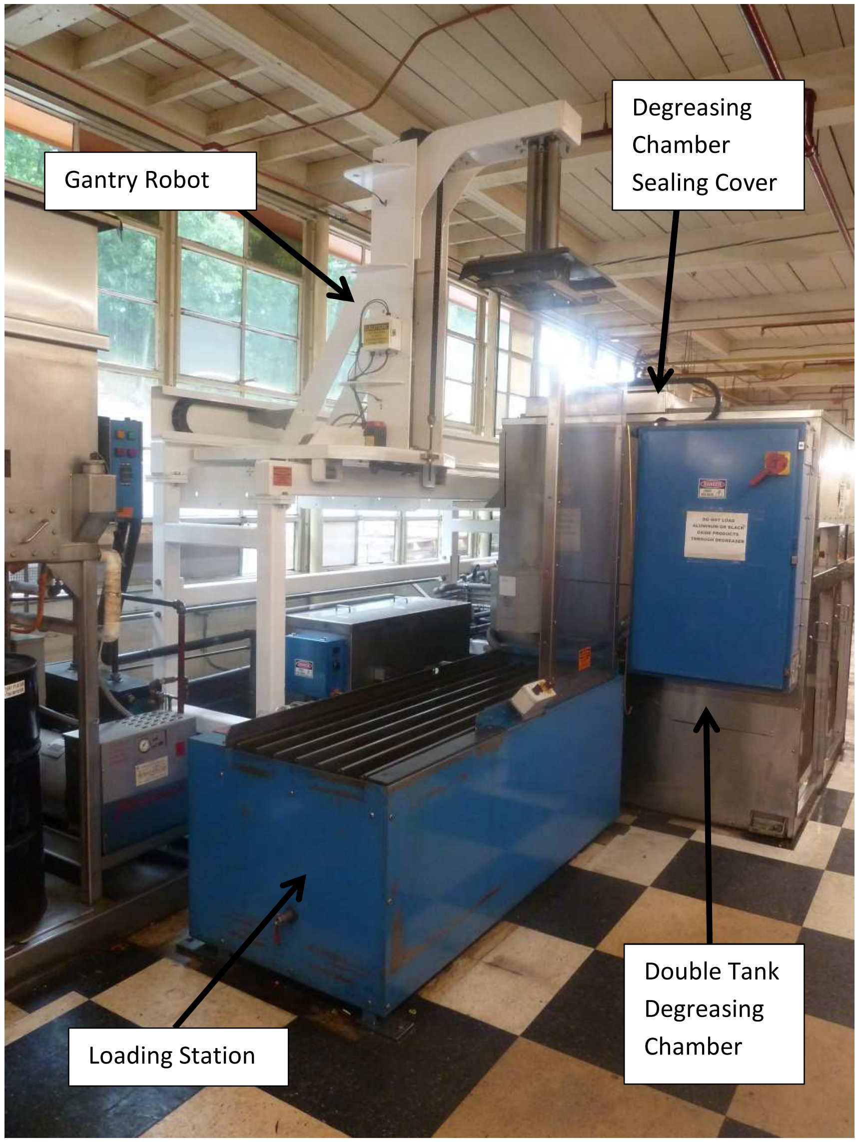
We commend the EPA for looking at Trichloroethylene use, and investigating whether its use in degreasing operations is being done in a safe and ecologically friendly manner. ***We respectfully request that the EPA consider: collecting further case study data at ongoing degreasing operations, producing a risk assessment report based upon observed exposure data and years employees are exposed, and determine whether workers are actually being exposed to harmful levels of Trichloroethylene instead of making new rules and policy based upon inaccurate assumptions and no factual data.***

With much appreciation for including us in this process.

Respectfully,
WHITTET-HIGGINS COMPANY

Andrew A.O. Brown

Exhibit 1.1 – Pictures of Greco Robot Actuated Degreasing System



Greco Robot Actuated Degreasing System - Front

Greco Robot Actuated Degreasing System - Rear

Greco Gantry Robot

Greco Robot Actuated Degreasing System – Programmable Logic Control (PLC)

Exhibit 1.2 - Whittet-Higgins Degreasing System Operating Data

PLC Control Ugraded & Retrofitted on September 12th, 2006

Time Elapsed since PLC Control Upgrade & Retrofit on Degreasing System	117	Months
Estimated Workdays Elapsed since PLC Control Upgrade & Retrofit on Degreasing System(*)	2,340	Days
Estimated Workhours Facility has Operated since PLC Control Upgrade & Retrofit on Degreasing System(^)	46,800	Hours

Baskets of Parts Processed Through System Since PLC Control Upgrade & Retrofit	2,521	Baskets
Cycle Time to Run One (1) Basket Through System	17.3	Minutes
Total Minutes Machine Has Operated Since PLC Control Upgrade & Retrofit	43,613.3	Minutes
Total Hours Machine Has Operated Since PLC Control Upgrade & Retrofit	726.9	Hours

Calculated Average Hours Solvent Degreaser Operated per Day	0.311	Hours
Calculated Average Minutes Solvent Degreaser Operated per Day	18.6	Minutes

(*) - Assumption of an average of 20 workdays per month

(^) - Facility runs from 6:30 AM to 2:30 AM Each Work Day - 80 Hours per Week