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AN ENVIRONMENTAL AND ENERGY LAW PRACTICE

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Admitted in PA and NJ

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Via Electronic and First Class Mail

Arleen Shulman
Chief, Air Resource Management
Department of Environmental Protection
Rachel Carson State Office Building
12th Floor, P.O. Box 8468
Harrisburg, PA 17105-8468

Re: Ozone Transport Commission Model Rule Development

Dear Ms. Shulman:

This comment letter is submitted on behalf of Accellent, Inc., a manufacturer of precision tubing and specialty medical devices located in Collegeville, Pennsylvania, in response to the Department's request for comment on the Ozone Transport Commission's ("OTC") development of model rules for stationary source control measures. The OTC has developed a draft model rule for solvent degreasing ("Model Rule"), which has been targeted for action by the OTC at its May, 2012 meeting. Accellent previously submitted comments on the Model Rule in August, 2009 and October, 2010, and those comments are incorporated herein by reference. Accellent supports the Model Rule as currently drafted and as amended from previous draft versions of the Model Rule.

Background Regarding Accellent

Accellent is a manufacturer of medical devices and precision tubing critical to the manufacture of medical devices. Accellent's manufacturing process is tailored precisely to the end use of its products. Its tubing consists of over 20 different alloys processed with more than 25 different lubricants, to over 200 different customers, primarily in the medical industry. These products consist of devices used in the body for diagnostic and surgical procedures as well as permanent implants for orthopedic and cardiovascular applications. In some cases, Accellent is the sole supplier of these devices to the medical industry.

Accellent operates two large batch vapor solvent cleaning machines with a solvent air interface greater than 1.21, square meters, utilizing trichloroethylene ("TCE") as the cleaning solvent. For many of its products, including most importantly its implantable medical devices,

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the degreasing process is a critical factor for product integrity and function. Such devices require a high level of metallurgical cleanliness, for which the use of TCE in the cleaning process is necessary. Although Accellent has researched and pilot tested various alternative cleaning solvents, no solvent other than TCE has been determined to be adequate to meet the strict cleanliness standards attendant to the manufacture of specialty medical devices.

Nearly 100 million feet of tubing is processed through Accellent's degreasers each year. Tubing is degreased in 40 foot straight lengths or in large coils. Both the inner and outer diameters of the tubes must be degreased at various points in Accellent's process, and may range in diameter from 0.003" to 0.750". Any change to the manufacturing process for these products require re-validation testing of the devices and some require subsequent regulatory approval from the Food and Drug Administration.

Current Control Systems

Accellent is subject to and complies with the federal National Emissions Standards for Hazardous Air Pollutants governing Halogenated Solvent Cleaning (the "NESHAP") under 40 CFR Part 63, Subpart T. The NESHAP was amended to reflect EPA's residual risk and technology review process, pursuant to which a facility-wide emission cap has been imposed on certain affected facilities (in addition to established controls requirements under the NESHAP). Narrow tube manufacturing facilities were excluded from the facility emission cap based on considerations that are unique to the industry, including the ability to use only specific cleaning solvents, and the operational considerations associated with the size and dimensions of the product. EPA commenced a reconsideration process focused in part on narrow tube facilities.

Additionally, Accellent worked extensively with the Department in response to the Department's request that Accellent voluntarily reduce TCE emissions from its Collegeville facility. After a thorough review of the few potentially viable process changes and/or control technologies that would reduce TCE emissions beyond existing NESHAP requirements, Accellent spent over \$2 million on the installation and operation of carbon adsorption systems at the Collegeville facility. Through that effort, Accellent has reduced actual emissions from the Collegeville facility by approximately 35%, and has also agreed to reductions in overall potential TCE emissions from the facility.

Comments on the Model Rule

1. The Model Rule Should Not Be More Stringent Than the NESHAP

As noted above, the NESHAP was reviewed and amended to further reduce emissions associated with halogenated solvent cleaning facilities. While the residual risk review process was not geared in the first instance toward compliance with ozone standards, it resulted in significant VOC reductions from facilities subject to the NESHAP. Accellent urges the OTC

and the Department to ensure that the Model Rule fairly reflects information gathered and developed during the lengthy NESHAP residual risk and technology review process. Further, to the extent the Model Rule is proposed or adopted in Pennsylvania, it should not be more stringent than the NESHAP for facilities subject to the NESHAP.

2. The Model Rule Should Not Prohibit the Use of Certain Solvents

As initially drafted, the Model Rule would have limited the ability to perform vapor degreasing operations using solvents with a VOC content greater than 25 g/l. In Accellent's case, the use of TCE in cleaning operations is critical to product integrity and safety. Accellent has explored other cleaning options, and has determined that none achieve the level of metallurgical cleanliness necessary for medical devices. If contaminants are present on the surface of the tube during heat treating operations subsequent to degreasing, these contaminants could compromise the corrosion resistance of the material and lead directly to corrosion, rusting and pitting of stainless steel devices such as catheters, stents and other implants in the body. Because the nature of Accellent's products leaves no margin for error, Accellent must be able to utilize TCE as a cleaning solvent unless or until an appropriate substitute can be identified and validated. Accellent supports the current draft of the Model Rule, which would not impose a VOC content limitation on solvents used in vapor degreasing operations.

3. The Model Rule Should Not Impose Any Additional Requirements for Degreaser Design or Control

As initially drafted, the Model Rule would allow utilization of solvents containing greater than 25 g/l VOC content only if degreasing was performed in an "airless / airtight cleaning system." The definition of "airless / airtight cleaning system" was restricted to certain types of degreaser design that are inappropriate for Accellent's cleaning operations.

During the NESHAP revision process, Accellent evaluated the feasibility of vacuum-to-vacuum technology and determined that the technology would not be feasible for several reasons. First, vacuum technology had been applied to cleaning machines that were generally three times smaller than those used by Accellent. Since there was no information to suggest that vacuum machines could be scaled up, and based on the inherently longer cycle times inherent to vacuum technology, Accellent estimated that two vacuum units would be necessary to replace each one of Accellent's degreasers. Installation of four new units would require Accellent to build an additional 8,000 square feet of building space. Second, top-loading degreasers are necessary to accommodate 40 foot lengths of tubing handled by Accellent. Since vacuum machines constructed to date are end-loading units, significant engineering difficulties would need to be addressed. Finally, Accellent's previous research and development testing of tubing coils cleaned in vacuum-to-vacuum units suggested that such units would not be effective in cleaning coils in a manner that meets the stringent cleanliness standards required for implantable medical devices. Even assuming that the engineering and quality difficulties could be overcome,

the budgetary estimates received by Accellent for the capital costs associated with implementation of the technology exceeded \$10.5 million and therefore was determined to be economically infeasible.

The current draft Model Rule correctly requires vapor degreasing operations to meet existing design, control and work practice standards identified in 25 Pa. Code section 129.63 for Degreasing Operations, which are in turn consistent with the NESHAP. Accellent supports this result, and believes that it is consistent with EPA's evaluation process undertaken during the NESHAP revision process.

4. The Medical Device Exemption Should be Clarified and Expanded to Include Degreasing Conducted During the Manufacture of Medical Devices

The Model Rule contains an exemption for the "cleaning of medical devices." The extent of this exemption is not clear. The Model Rule should clarify that degreasing activities conducted during the manufacture of medical devices and the precision tubing critical to the manufacturer of medical devices would be exempt from the Model Rule.

5. The Model Rule Should Not Impose Additional Requirements on Accellent

To the extent adopted by the OTC or promulgated in Pennsylvania, the Model Rule should not impose additional control or emission reduction requirements on facilities, like Accellent, which have proactively reduced VOC emissions.

Accellent has identified carbon adsorption as the only viable emission control technology for its degreaser emissions. Working closely with PADEP, Accellent undertook a voluntary installation of carbon systems on each of its two large degreasers. Each system was custom designed to serve Accellent's degreasers, and was completed in a very short period of time spanning less than 15 months from commencement of engineering to completion of installation. Accellent's installation of the carbon system was a continuation of its aggressive efforts over several years to reduce overall emissions from the facility.

Using 1990 as a baseline year, Accellent has reduced VOC emissions from the Facility by over 90%. Actual VOC emissions in 1990 were 487 tons (477 tons from degreasing), primarily of 1,1,1 trichloroethane ("TCA"). Through its voluntary participation in EPA's 33/50 program for the phaseout of TCA, along with degreaser modifications to meet the requirements of the Halogenated Solvent Cleaning NESHAP and process modifications including solvent substitution, Accellent reduced VOC emissions from the Facility to a potential to emit of 94 tons per year (as set forth in its Title V permit, originally issued in 2001). Despite increasing production levels by 25% since 2001, Accellent was consistently able to maintain TCE emissions well below its permitted potential to emit, with 2006 actual emissions at 68 tons. As a result of

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the carbon system installation in 2007 and 2008, Accellent has been successful in reducing actual emissions by another 35%, and has accepted limitations on facility potential to emit. Given this proactive approach toward emission reduction, and the identification and implementation of control retrofits, Accellent should not be subject to further requirements under the Model Rule.

I appreciate this opportunity to comment on the Model Rule on behalf of Accellent, Inc. and would be happy to discuss these comments further at your convenience.

Very truly yours,



Carol F. McCabe

For MANKO, GOLD, KATCHER & FOX, LLP

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cc: Robert P. Deist

