



# PERSPECTIVES

on Georgia's Environment

A Publication of the Environmental Law Section of the State Bar of Georgia

Winter 2013

## Meth Residues: A Hidden Environmental Condition in Georgia

By Matthew Parker, Senior Industrial Hygienist, Cardno ATC

First it was asbestos, then lead based paint, followed by toxic mold. Now, the latest panic-inducing environmental hazard is contamination due to methamphetamine (meth) production. Property owners and attorneys face a new breed of lawsuits, and consultants and foreclosing lenders face novel due diligence challenges stemming from the meth epidemic spreading throughout the nation. This environmental crisis is just one consequence of the massive expansion of small methamphetamine drug labs using readily available over-the-counter drugs like ephedrine and pseudoephedrine. The Drug Enforcement Administration (DEA) has seized increasing quantities of meth from these drug labs (also called meth kitchens or clandestine labs) each year with the number of meth lab seizures rising from 7,334 in 2008 to 10,287 in 2011.<sup>1</sup> More important to Georgia residents, Atlanta has reportedly become the East Coast distribution hub for meth smuggled into the United States,<sup>2</sup> and the DEA has identified 362 labs in the state of Georgia on its Clandestine Lab Registry,<sup>3</sup> with many more likely still undiscovered. These labs are hazardous to human health and the environment, lead to significant damages and cleanup costs and pose many quandaries in their regulation and remediation.

### An Epidemic Problem in Georgia

Between 2007 and 2011, the U. S. Drug Enforcement Agency reported a steady rise of meth lab seizures with the number peaking at over 11,000 in 2010.<sup>4</sup> Georgia's own statistics mirror this trend with meth lab seizures rising to almost 200 within the same time period.<sup>5</sup> The problem is not limited to low income areas; many drug labs have been discovered in large expensive homes<sup>6</sup> and Class A apartment

complexes. The Georgia portion of the Department of Justice National Clandestine Laboratory Register website is nine pages long and references not only homes in rural Georgia counties but also large suburban homes in affluent Atlanta areas.

Methamphetamine itself is a potent synthetic drug that is a stimulant to the central nervous system.<sup>7</sup> It is also called "speed," "crank," "crystal" and "ice," and it gives the user a "rush" that often lasts longer than cocaine. Meth may be injected, snorted, taken orally or smoked and generally gives a person periods of high energy and rapid speech. However, chronic users also experience severe depression, delusions, hallucinations, paranoia and violent behavior.

Environmental hazards arise because meth labs themselves are relatively easy to set up using only the most basic of equipment (*e.g.*, blenders, soda bottles, camp stoves, coffee filters, propane tanks, strainers) and are often located in makeshift laboratories in homes, apartments or hotel rooms. To further compound the problem by making its production even simpler, the process involves cooking everyday cold medicine containing pseudoephedrine with common household chemicals such as ether, denatured alcohol, lantern fuel, acetone, paint thinner, kerosene, battery acid, lithium, brake cleaner, as well as less commonly found domestic chemicals such as anhydrous ammonia, red phosphorous, iodine, and reactive metals. The mixing of these chemicals poses significant fire risks not only to the individuals producing the drug, but also to anyone in the surrounding area, including children, neighbors, and passersby.

Even when fire or explosion does not occur, simple exposure to meth's toxic production chemicals poses a variety

### Contents

|   |   |
|---|---|
| Adjacency, Interrupted: <i>Summit Petroleum Corporation v. U.S. EPA</i> ..... | 4 |
| 2013 Newsletter Editorial Board .....   | 8 |

|   |    |
|---|----|
| 2013 Environmental Law Section Officers ..... | 8  |
| OSAH Reporter .....                           | 9  |
| Pharmaceutical Waste Regulation:.....         | 10 |
| What a Long, Strange Trip It's Been .....     | 14 |

of health risks, including intoxication, dizziness, nausea, disorientation, lack of coordination, pulmonary edema, serious respiratory problems, severe chemical burns and damage to internal organs.<sup>8</sup> In addition, contamination remains in walls, carpets, furniture, and even personal belongings (*e.g.*, clothes, blankets, stuffed animals) long after production has ceased, and the health risks from long-term, low-level exposures to meth residue chemicals are still unknown.<sup>9</sup> And even more concerning, for every pound of meth synthesized, five or more pounds of hazardous waste materials or chemicals are generated.<sup>10</sup> These wastes are often left on the premises, dumped down local septic systems, or illegally dumped in backyards, open spaces, and ditches along roadways<sup>11</sup> causing contamination of the soil and nearby water supplies.

## The Cleanup of Meth Labs

The U. S. Environmental Protection Agency has issued voluntary guidance for meth lab cleanup, but the guidance does not set requirements and only suggests methods for approaching the problem.<sup>12</sup> Several states have developed cleanup standards for meth contamination of indoor surfaces.<sup>13</sup> These standards can range from as low as 0.05  $\mu\text{g}/100\text{cm}^2$  to 0.5  $\mu\text{g}/100\text{cm}^2$ .<sup>14</sup> The most common standard is 0.1  $\mu\text{g}/100\text{cm}^2$ .<sup>15</sup> Yet, none of these standards are based on toxicity criteria or on estimates of potential exposure that might result from contact with meth contaminated surfaces.<sup>16</sup> They are not risk-based standards and are often legislatively enacted levels based on limits of detection or economic feasibility.<sup>17</sup>

Despite Georgia's rising number of clandestine meth labs, the state does not have either a cleanup standard or guidelines. Thus, many Georgia property owners or managers limit their cleanup to new paint and new carpet, which can mask many of the signs that a lab was present.<sup>18</sup> One recent Cardno ATC project is a good example of the difficulties that the absence of a standard creates. A home in an upscale neighborhood was raided by police due to suspicious activity, and they discovered a mobile methamphetamine lab in the garage. The lab equipment was seized as evidence, and a state contractor removed and properly disposed of the bulk chemicals. The responsibility for residual contamination, however, was left to the property owner, who in this case was

not the occupant of the dwelling during this illegal activity. The property owner retained Cardno ATC to survey the property, and Cardno ATC found methamphetamine residues on surfaces in every room of the house. Although the meth lab was operated in the garage, apparent indoor use had contaminated the interior of the home as well.

Nevertheless, with no regulations or guidance in Georgia setting the cleanup standard for meth lab contamination, the methods and clearance sampling criteria were discretionary. Cardno ATC, therefore, reviewed the available data, researched the options, and recommended 0.1  $\mu\text{g}/100\text{cm}^2$  as the clearance criteria. To achieve this low threshold, Cardno ATC and the Property Owner removed the drywall and performed extensive surface cleaning and sanding. The costs of this remediation effort exceeded \$100,000, and yet, the home still had diminished value at closing. Unfortunately, this result is not unusual and thereby demonstrates the substantial economic damage that can be caused by these meth lab operations.

## The Legal Challenges of Meth Labs

Because meth labs are clandestine by design and the evidence of their prior operation is easy to hide with paint and new carpet, uncovering their hazards is challenging and often comes too late. Most landlords and property owners themselves do not know about a meth lab until law enforcement discovers it or the evidence is found when a tenant moves out. Thus, in many cases, subsequent tenants or homebuyers are not informed of the previous or possible meth contamination by their landlords, property managers, or sellers. Their first awareness might be a neighbor telling them the history of their apartment or the development of an exposure symptom (*e.g.*, rapid speech, rapid breathing, increased body temperature, increased blood pressure, paranoia, insomnia, or loss of appetite).<sup>19</sup>

To combat this problem, at least 23 states have recently passed laws mandating that sellers disclose to buyers that a home was a former meth lab.<sup>20</sup> In addition, laws mandating sellers clean up meth houses before selling them are on the books in at least 22 states.<sup>21</sup> Georgia's effort to do the same did not succeed.<sup>22</sup> Therefore, in Georgia, property owners and realtors may disclose what they know, but these labs are generally hidden hazards of which the seller, landlord or real estate agent is unaware. Whether these issues will be resolved by the Georgia courts remains to be seen, although other state courts have held selling property owners and real estate agents with knowledge liable for failure to disclose that a home was formerly a meth lab operation.<sup>23</sup>

In Georgia, however, the over-the-counter availability of ephedrine and pseudoephedrine has now been limited by behind-the-counter point of sale controls, quantity limitations, photo ID requirements, and information sharing,<sup>24</sup> all of which have hampered the criminal producers' ability to collect the



required quantities of these precursor drugs. This has had a two-fold effect. It has reduced the total number of labs, but has also spurred some supersized labs using smuggled precursors, as well as many smaller, personal use, or mobile labs. These larger labs<sup>25</sup> increase the volume of production and the related wastes or contamination, while smaller labs make the contamination more difficult to root out.

Accordingly, although this new law has perhaps slowed the escalating meth-lab epidemic, it is clear that meth will continue to create environmental concerns for property owners, tenants and foreclosing lenders. Because there is no cleanup standard or disclosure rule yet, either nationally or within Georgia, the contamination caused by a former meth lab may still create liability for a property owner or significantly diminish a property's market value. Thus, it is important that attorneys and consultants are aware of this issue when performing environmental due diligence<sup>26</sup> on all properties, particularly homes, apartments, hotels, and other residential structures which are often overlooked as having any serious potential for significant environmental hazards.

*Matthew Parker is a Senior Industrial Hygienist with Cardno ATC, a nationwide engineering and environmental services firm. Cardno has assisted property owners, real estate firms, tenants, and attorneys in documenting the levels of meth contamination and the related environmental impacts from its production.*

(Endnotes)

- 1 DEA: United States Drug Enforcement Administration, <http://www.justice.gov/dea/resource-center/statistics.shtml#seizures> (last visited Dec. 7, 2012).
- 2 Georgia Meth Project, <http://www.GeorgiaMethProject.org> (last visited Dec. 12, 2012).
- 3 DEA: United States Drug Enforcement Administration, <http://www.justice.gov/dea/clan-lab/clan-lab.shtml> (last visited Dec. 7, 2012).
- 4 DEA: United States Drug Enforcement Administration, <http://www.justice.gov/dea/resource-center/meth-lab-maps.shtml> (last visited Dec. 12, 2012).
- 5 *Id.* See also, Georgia Meth Project, Meth Newsletter, [http://georgia.methproject.org/News/newsletters/GA\\_Meth\\_Newsletter\\_Spring\\_2012.pdf](http://georgia.methproject.org/News/newsletters/GA_Meth_Newsletter_Spring_2012.pdf) (last visited Feb. 4, 2013).
- 6 HD News, Deputies bust meth lab in upscale Evans home, <http://www.wrdw.com/home/headlines/507713/html> (last visited Jan. 28, 2013).
- 7 Georgia Meth Project, The Meth Project: Methamphetamine Facts, [http://georgia.methproject.org/documents/Fact\\_Sheet\\_Methamphetamine.pdf](http://georgia.methproject.org/documents/Fact_Sheet_Methamphetamine.pdf) (last visited Jan. 28, 2013).
- 8 *Id.*
- 9 U. S. Environmental Protection Agency, VOLUNTARY GUIDELINES FOR METHAMPHETAMINE LABORATORY CLEANUP (August 2009).
- 10 National Drug Intelligence Center, Methamphetamine Laboratory Identification and Hazards and Fast Facts, <http://www.justice.gov/archive/ndic/pubs7/7341p.pdf> (last visited Jan. 28, 2013).
- 11 See United States Environmental Protection Agency, RCRA HAZARDOUS WASTE IDENTIFICATION OF METHAMPHETAMINE PRODUCTION PROCESS BY-PRODUCTS (Sept. 26, 2008).
- 12 U. S., Environmental Protection Agency, VOLUNTARY GUIDELINES FOR METHAMPHETAMINE LABORATORY CLEANUP (August 2009).
- 13 See e.g., State of North Carolina, ILLEGAL METHAMPHETAMINE LABORATORY DECONTAMINATION AND RE-OCCUPANCY GUIDELINES

- (April 2005) (guidelines attempt to set out processes for decontamination of a site including removal of the wastes, removal of all porous materials, evaluation and possible removal of plumbing and ventilation systems and post-decontamination testing); Colorado Department of Public Health and Environment, SUPPORT FOR SELECTION OF A CLEANUP LEVEL FOR METHAMPHETAMINE AT CLANDESTINE DRUG LABORATORIES (February 2005) (considered possibly the most extensive meth cleanup regulations including decontamination, sampling, and reporting).
- 14 EPA Voluntary Guidelines, p. 6.
- 15 See e.g., WASH. ADMIN. CODE 246-205-541(1) (setting decontamination standard for methamphetamine as 0.1 µg/100cm<sup>3</sup>).
- 16 EPA Voluntary Guidelines, p. 6.
- 17 California's Department of Toxic Substances Control has announced a calculated health-based target remediation standard of 1.5 µg/100cm<sup>2</sup> CAL. HEALTH AND SAFETY CODE §25400.16. This level is reportedly set at what is believed to be conservative level to account for the scientific uncertainty in the interest of protecting human health. EPA Voluntary Guidelines, p. 6.
- 18 See e.g., FoxNews.com, Miller, Joshua Rhett, "Meth Rehab: Former labs a nightmare for unwitting homebuyers" (June 27, 2012), <http://www.FoxNews.com> (last visited Jan. 16, 2013). Family purchased home that had passed the standard home inspection, but later discovered that the studs within the walls were soaked with dangerous chemicals. Family chose to rebuild for a cost of \$184,000 rather than repair and remediate for a cost of \$90,000.
- 19 See e.g., FoxNews.com, "Georgia man finds suspected meth labs under rental home", (published March 21, 2012) <http://www.FoxNews.com/us/2012/03/21/georgia-man-finds-suspected-meth-labs-under-rental-home/> (last visited Oct. 17, 2012).
- 20 The following states have various disclosure requirements: Washington, Oregon, California, Nevada, Montana, Utah, Arizona, Wyoming, Colorado, New Mexico, South Dakota, Oklahoma, Texas, Minnesota, Missouri, Arkansas, Louisiana, Illinois, Indiana, Kentucky, West Virginia, New Hampshire and Alaska.
- 21 The 22 states include the following: Washington, Oregon, Idaho, Montana, California, Nevada, Wyoming, Colorado, Arizona, New Mexico, Alaska, Hawaii, Nebraska, Minnesota, Indiana, Arkansas, Louisiana, Kentucky, Tennessee, West Virginia, New Hampshire, and North Carolina.
- 22 Georgia Senate Bill 15, 2009.
- 23 See e.g., *Bloor v. Fritz*, 180 P.3d 805 (Wash. Ct. App. 2008) (rescinding contract for sale of home and awarding damages against selling homeowner and real estate agent based upon negligent misrepresentation and failure to disclose under applicable disclosure law); *Slacks v. The Landmark Co. et al.*, 267 P.3d 6 (Mont. 2011)(found County negligent in failing to list home as contaminated pursuant to relevant regulations such that buyer and agent were not aware of contamination which forced home buyer to abandon the home and all of their personal belongings).
- 24 O.C.G.A. § 16-13-30.3.
- 25 See e.g., Police Link, Meth 'Super Lab' Raid One of Biggest Busts in History (Dec. 1, 2010) <http://policelink.monster.com/news/articles/147616-meth-super-lab-raid-one-of-biggest-busts-in-history> (last visited Jan. 28, 2013) (police found 984 pounds of meth worth approximately \$44 million in Gwinnett County, Georgia home).
- 26 As with asbestos, lead-based paint, mold and radon, meth contamination is not within the standard scope of an ASTM E1527-05 Phase I investigation and must be specifically included in the relevant scope of work.



# Adjacency, Interrupted: *Summit Petroleum Corporation v. U.S. EPA*

By Jennifer A. Simon, Kazmarek Geiger & Laseter LLP

A recent Sixth Circuit opinion overturned longstanding U.S. Environmental Protection Agency (EPA) Clean Air Act (CAA) policy. In *Summit Petroleum Corporation v. U.S. EPA*, 690 F.3d 733 (6th Cir. 2012), the court curtailed EPA's expansive interpretation of the term "adjacent" for purposes of aggregating sources under the CAA by ruling that "adjacent" must be understood as a concrete "physical and geographical" concept.<sup>1</sup> At least within the Sixth Circuit's jurisdiction, this ruling invalidates EPA's approach of evaluating facilities' adjacency based on their functional relationship rather than their proximity. EPA has stated the decision will not impact its practice elsewhere, but additional litigation on the subject is sure to follow until other circuits or the Supreme Court provide final resolution.

## I. Background

Many CAA provisions, such as those pertaining to Title V permitting and the Prevention of Significant Deterioration (PSD) requirements, revolve around certain groupings of air pollution sources. For example, a Title V permit is required to operate a "major source," and the regulations define "major source" as a "stationary source" or "any group of stationary sources that are located on one or more contiguous or adjacent properties, ... are under common control of the same person ... [and] have the same two-digit code as described in the Standard Industrial Classification Manual, 1987."<sup>2</sup> Similarly, the PSD regulations require a permit prior to the construction or modification of a major "stationary source," which includes "all of the pollutant emitting activities which belong to the same industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same person (or persons under common control)."<sup>3</sup>

In addition, by policy, EPA has expanded the set of sources that must be aggregated to include any facilities with a different SIC code that provide support to an adjacent central operation.<sup>4</sup> EPA defines such "support facilities" as "those which convey, store, or otherwise assist in the production of the principal product."<sup>5</sup>

Thus, EPA looks to three factors to determine which sources must be aggregated under the CAA: (1) whether the sources possess the same SIC codes or otherwise provide support to an adjacent source; (2) whether the sources are located on contiguous or adjacent land; and (3) whether the sources are under common control. The analysis of these factors is riddled with nuances and complexities and has given

rise to a large body of policy statements, guidance documents and public correspondence. The definition of "adjacent" plays prominently in two of the factors, and EPA has consistently interpreted the concept expansively, notwithstanding a more limited initial explanation.

In the Preamble to the Aug. 7, 1980, final PSD regulations, EPA explained its general intent to follow "the common notion of a plant."<sup>6</sup> In some instances, distance alone would be determinative. Specifically, EPA would not find facilities twenty miles apart to be adjacent or contiguous.<sup>7</sup> Even continuous, "long-line," operations should not be considered adjacent or contiguous under EPA's original interpretation.<sup>8</sup> Further, EPA rejected a "functional" method of grouping activities under the definition of "source" in favor of using SIC codes, because a "functional" analysis would decrease predictability and increase the administrative difficulty.<sup>9</sup> In practice, the aggregation of support facilities with their principal source and a liberal reading of the adjacency requirement have made that discussion moot.

Even while stating its intention to abide by those initial policy statements, EPA quickly moved toward a more functional rather than literal reading of the term "adjacent." For example, only a year later in 1981, EPA responded to a question from its Region V<sup>10</sup> as to whether two General Motors plants should be aggregated for purposes of compliance with PSD regulations.<sup>11</sup> The two plants were located one mile apart, and though they were connected by a rail line, products were transported between the facilities by truck. The EPA Administrator concurred with its Region V chief that the two facilities were "functionally equivalent to a source."<sup>12</sup>

This expansive interpretation continued through a series of determinations EPA issued in the 1990s and 2000s. In 1996, EPA concurred with its Region III's conclusion that an Anheuser-Busch brewery and landfarm were a single source, even though they were six miles apart, because the brewery disposed of its wastewater at the landfarm via a pipeline connection.<sup>13</sup> EPA based its conclusion on the presence of the pipeline and that "the landfarm operation is an integral part of the brewery operations."<sup>14</sup>

By 1997 EPA had abandoned its 20-mile threshold from the Preamble to the Aug. 7, 1980, final PSD regulations. EPA advised that a Great Salt Lake Minerals plant should be considered a single source with its pump station located 21.5 miles away on the other side of a lake.<sup>15</sup> A dedicated channel transported pre-concentrated brine between the pump

station and the processing plant. EPA explained that “[d]istance between the operations is not nearly as important in determining if the operations are part of the same source as the possible support that one operation provides for another.”<sup>16</sup>

EPA also made clear that no actual physical connection is required for two facilities to be considered adjacent support facilities. EPA even found dictionary definitions of “contiguous” and “adjacent” that included “in close proximity without actually touching; near” and “near or close; next or contiguous.”<sup>17</sup> Relying on those generous definitions, EPA concluded a support facility was “adjacent” to its main plant because the “dependent nature” of the facilities’ operations meant they met the “common sense notion of a plant.”<sup>18</sup>

EPA made further use of this expanded concept of adjacency when it decided two facilities, 3.7 miles from each other, were adjacent and comprised an “integrated steel mill.”<sup>19</sup> EPA explained, “Although the two sites are separated by Lake Calumet, landfills, I-94, and the Little Calumet River, USEPA considers that the close proximity of the sites, along with the interdependency of the operations and their historical operation as one source, as sufficient reasons to group these two facilities as one.”<sup>20</sup>

In each of these determinations, EPA was generally attempting to determine whether the two facilities in question met its “common sense notion of a source.” Relevant to this analysis was whether the facilities’ locations were chosen to facilitate integration, if materials and employees were routinely transported between the facilities, and if the two facilities collaboratively manufactured a common product.<sup>21</sup> This “common sense notion of a source” is based on “the functional inter-relationship of the facilities, and is not simply a matter of the physical distance between two facilities.”<sup>22</sup> Therefore, EPA found that American Soda’s mine was adjacent to its processing plant, even though they were located 35-40 miles apart, due to their pipeline connection and functional interdependence.<sup>23</sup>



EPA has also stated its position that two facilities could be considered adjacent “strictly on the basis of proximity without regard to whether the facilities are dependent on each other or physically connected in some way.”<sup>24</sup> Nevertheless, where two bulk gasoline terminals were separated by nearly a mile with no physical connection and operated entirely independently, EPA determined the two facilities could be considered separate sources.<sup>25</sup>

Conversely, geography could in some instances be largely irrelevant, and EPA has cautioned that “a specific distance between pollutant emitting activities has never been established by USEPA for determining when facilities should be considered separate or one source for PSD and title V purposes.”<sup>26</sup> Rather, “[w]hether facilities are contiguous or adjacent is ... based on the relationship between the facilities.”<sup>27</sup> For example, where General Dynamics manufactured certain components at its central plant that were then further processed at outlying facilities (though 8 miles distant), EPA determined the facilities must all be aggregated for Title V purposes.

Finally, in 2009 EPA concluded two Alcoa, Inc. aluminum smelter facilities located 3.4 miles apart were adjacent due to the extensive truck transportation of intermediate products and employees between the two sites.<sup>28</sup> EPA explained that “whether or not two facilities are adjacent depends on the ‘common sense’ notion of a source and the functional interrelationship of the facilities and is not simply a matter of the physical distance between the two facilities.”<sup>29</sup> EPA concluded the two facilities shared such a functional interrelationship.

EPA briefly published a guidance document describing its approach to single source determinations, although it withdrew that document just two years later.<sup>30</sup> EPA’s guidance pertained to the oil and gas industry, where well sites can be located hundreds of miles from the natural gas processing plant. EPA explained that its adjacency determinations are rooted in whether the operations in question are “connected to” or “nearby” one another and that typically it has considered the sources’ “operational dependence” and “proximity” in making its analysis.<sup>31</sup> “Operational dependence” occurs when the activities rely on each other for their operations.<sup>32</sup> However, EPA decided it would not consider “operational dependence” in its single source determinations for the oil and gas industry, “because it would embroil the Agency in precisely the fine-grained analysis [it] intended to avoid, and it would potentially lead to results which do not adhere to the common sense notion of a plant.”<sup>33</sup> In limiting its analysis to the sources’ proximity, EPA further advised that aggregating geographically-dispersed well site activities with their downstream processing plant “defies the concept of contiguous and adjacent.”<sup>34</sup> However, two years later EPA withdrew that guidance, explaining proximity should not be the overwhelming factor and each decision should be made on a case-by-case basis.<sup>35</sup>



## II. *Summit v. EPA*

In 2010 EPA considered whether Summit Petroleum Corporation's gas wells and associated flares should be considered a single source with Summit's gas sweetening plant.<sup>36</sup> EPA noted that "it has historically interpreted the term to include concepts other than the physical distance between two facilities" and that "emissions units need not be on properties that are physically touching in order to be ... aggregated."<sup>37</sup> "In fact, EPA has repeatedly included an evaluation of the nature of the relationship between the facilities and the degree of interdependence between them in determining whether multiple non-contiguous emissions points should be considered a single source."<sup>38</sup> Therefore, EPA did not find it dispositive that several of the wells were located over a mile from the central plant and were separated by other intervening properties. Instead, EPA noted that the wells and the plant were highly interdependent and connected via a collection system. As a result, EPA concluded the wells and plant were "adjacent given the common purpose of producing saleable, sweet natural gas" and met the "common sense" notion of a single facility.<sup>39</sup>

Summit challenged EPA's single source determination, and the Sixth Circuit vacated that determination in *Summit Petroleum Corporation v. U.S. EPA*. The court found it "unreasonable and contrary to the plain meaning of the term 'adjacent'" that EPA equated "functional relatedness" with "physical adjacency."<sup>40</sup> The court considered dictionary definitions, judicial precedent and EPA's own historical decisions. First, the court found that dictionaries all used geographical, as opposed to functional, terms to define "adjacent," including the following:

- American Heritage Dictionary of the English Language, *available at* [www.ahdictionary.com](http://www.ahdictionary.com): "[c]lose to; lying near . . . [n]ext to, adjoining"
- Meriam-Webster Dictionary, *available at* [www.meriam-webster.com](http://www.meriam-webster.com): "not distant: nearby <the city and *adjacent* suburbs>; having a common endpoint or border <*adjacent* lots> . . . ; immediately preceding or following"

- Oxford Dictionaries, *available at* [www.oxforddictionaries.com](http://www.oxforddictionaries.com): "next to or adjoining something else; *adjacent rooms*; *the area adjacent to the fire station*"<sup>41</sup>

In its analysis of the relevant case law, the court relied heavily on the Supreme Court's decision in *Rapanos v. United States*, 547 U.S. 715 (2006) to find that "adjacent" means "adjoining" or "physically abutting," not "functionally related."<sup>42</sup>

Following its analysis of the dictionary and judicial definitions, the court concluded the term "adjacent" was unambiguous and, therefore, EPA's interpretation of it was not entitled to deference and even ran counter to the term's plain meaning. Nevertheless, the court reasoned that, even giving the agency deference, EPA's interpretation was unreasonable, because it was not in line with the history of the CAA and EPA's own guidance.

In analyzing the pertinent CAA history, the court noted EPA's original rejection of a "functional" approach to aggregating sources in favor of using SIC codes.<sup>43</sup> The court considered this rejection inconsistent with EPA's present position that "adjacent" and "functionally related" could be equivalent.<sup>44</sup> EPA's 2007 guidance to the oil and gas industry also specifically concluded that because "operational dependence" was an ineffective criterion for assessing adjacency when well sites might be located hundreds of miles from the processing plant, EPA would only consider the sources' proximity. EPA even cited to that guidance in its initial correspondence to Summit and only withdrew that guidance shortly before (or possibly even after) it issued its final determination.<sup>45</sup> Finally, the court found the Summit dispute a case-in-point that EPA's test for determining whether sources should be aggregated was unmanageable and unreasonable. Even before the litigation commenced, the parties dialogued and exchanged written correspondence on the issue for over five years, costing both Summit and EPA considerable money and time. Since EPA purported to create a test that would not be "administratively burdensome,"<sup>46</sup> the court reasoned the present iteration had wandered far from that original intent.

The court ordered EPA to use instead the "ordinary, i.e., physical and geographical" meaning of the word "adjacent."<sup>47</sup> The court remanded the case for EPA to conduct "a reassessment of Summit's Title V source determination request in light of the proper, plain-meaning application of the requirement that Summit's activities be aggregated only if they are located on physically contiguous or adjacent properties."<sup>48</sup>

## III. Next Steps

The *Summit Petroleum* decision was issued on Aug. 7, 2012. EPA then filed a petition for rehearing, which the Sixth Circuit denied on October 29, 2012. Any petition for a writ of certiorari to the U.S. Supreme Court would have been due on January 28, 2013,<sup>49</sup> and, as of the date of this writing,





no petition appears to have been filed. Therefore, *Summit Petroleum* stands as the law within the Sixth Circuit.

*Summit Petroleum* will now affect longstanding EPA policy and practice<sup>50</sup> in making single source determinations at least within the Sixth Circuit. On Dec. 21, 2012, EPA released a guidance document confirming that *Summit Petroleum* would indeed change its protocol in states within the Sixth Circuit's jurisdiction (Michigan, Ohio, Tennessee and Kentucky).<sup>51</sup> However, EPA decided that in all other states, it would "continue to make source determinations on a case-by-case basis using the three factor test ... consider[ing] both proximity and interrelatedness in determining whether emission units are adjacent."<sup>52</sup>

#### IV. Implications in Georgia

The Georgia Environmental Protection Division's (EPD) policy is to consider any two sources greater than 20 miles apart to be separate sources and to evaluate any two sources less than 20 miles apart on a case-by-case basis.<sup>53</sup> For sources separated by less than twenty miles, EPD's policy could in some instances conflict with *Summit Petroleum*. Of course, *Summit Petroleum* is not binding on EPA's Region IV or on EPD and, as EPA explained in its recent guidance, will not immediately affect single sources determinations in Georgia. Nevertheless, the Sixth Circuit's decision is important if its reasoning gains traction in other circuits or at EPA. At a minimum, increased litigation of single source determinations is likely, especially as courts across the country appear to be taking a harder look at the limits of EPA's discretion and statutory authority.<sup>54</sup>

##### (Endnotes)

- 1 690 F.3d at 735.
- 2 40 C.F.R. §§ 70.2; 71.2 (emphasis added). See also 42 U.S.C. § 7661a(a).
- 3 40 C.F.R. §§ 51.166(b)(5)(6); 52.21(b)(5), (6) (emphasis added). See also 42 U.S.C. §§ 7475(a)(1), 7479(2)(C).
- 4 See Preamble to the August 7, 1980, final Prevention of Significant Deterioration (PSD) regulations, 45 FR 52676;

- Preamble to Revised Part 51 and Part 70, Draft, February 18, 1998.
- 5 Preamble to the August 7, 1980, final Prevention of Significant Deterioration (PSD) regulations, 45 FR 52676.
- 6 45 FR 52676, at 52680.
- 7 See 45 FR 52676 ("One commenter asked, however, whether EPA would treat a surface coal mine and an electrical generator separated by 20 miles and linked by a railroad as one 'source,' if the mine, the generator, and the railroad were all under common control. EPA confirms that it would not. First, the mine and the generator would be too far apart. Second, each would fall into a different two-digit SIC category.").
- 8 See 45 FR 52676 ("EPA has stated in the past and now confirms that it does not intend 'source' to encompass activities that would be many miles apart along a long-line operation. For instance, EPA would not treat all of the pumping stations along a multistate pipeline as one 'source.'").
- 9 See *id.*
- 10 The CAA authorizes the owner or operator of a source to request an official determination from EPA regarding the applicability of the CAA regulations to certain sources or activities. See, e.g., 40 CFR 60.5; 40 CFR 61.06; 40 CFR 71.3(e). In addition, EPA responds to requests from its regional offices and from state administrators for determinations of CAA applicability to particular sources. See, e.g., EPA, "How to Review and Issue Clean Air Act Applicability Determinations and Alternative Monitoring," Feb. 1999, available at <http://www.epa.gov/reg3artd/airregulations/delegate/appdet.pdf>.
- 11 See Memorandum from EPA Division of Stationary Source Enforcement to EPA Region 5 (Jun. 30, 1981), available at <http://www.epa.gov/region7/air/nsr/nsrmemos/defsorce2.pdf>.
- 12 *Id.*
- 13 Memorandum from the Office of Air Quality Planning and Standards (OAQPS) to EPA Region 8 (Aug. 27, 1996), available at <http://www.epa.gov/region7/air/title5/t5memos/abnt.pdf>.
- 14 *Id.*
- 15 See Letter from EPA Region XIII to the Utah Department of Environmental Quality (Aug. 8, 1997), available at <http://www.epa.gov/region7/air/title5/t5memos/util-at1.pdf>.
- 16 *Id.*
- 17 Letter from EPA Region X to Andy Ginsberg, Oregon Department of Environmental Quality (Aug. 7, 1997), available at <http://www.epa.gov/region7/air/title5/t5memos/util-at2.pdf> (citing The Random House Dictionary of the English Language, College Edition).
- 18 *Id.*
- 19 Letter from EPA Region 5 to the Illinois Environmental Protection Agency (Mar. 13, 1998), available at <http://www.epa.gov/region7/air/title5/t5memos/acme.pdf>.
- 20 *Id.*
- 21 See Letter from EPA Region 8 to the Utah Division of Air Quality (May 21, 1998), available at <http://www.epa.gov/region7/air/title5/t5memos/util-trl.pdf>.
- 22 Letter from EPA Region 8 to Colorado Department of Public Health and Environment (Apr. 20, 1999), available at <http://www.epa.gov/region7/air/nsr/nsrmemos/amersoda.pdf>.
- 23 *Id.*
- 24 See Memorandum from Winston Smith, Director Air, Pesticides and Toxics Management Division to Randy C. Poole, Air Hygienist 11 (May 19, 1999), available at <http://www.epa.gov/region7/air/title5/t5memos/we1999.pdf>.
- 25 *Id.*

- 26 Letter from EPA to IEPA (Mar. 14, 2006), available at <http://www.epa.gov/Region7/air/title5/t5memos/general2006.pdf>.
- 27 *Id.*
- 28 See Letter from Steven C. Riva, U.S. EPA, to Robert Lenney, Alcoa Inc. (Mar. 9, 2009), available at <http://www.epa.gov/region7/air/nsr/nsrmemos/alcoany.pdf>.
- 29 *Id.*
- 30 See Memorandum from William L. Wehrum, Acting Assistant Administrator, to Regional Administrators, Source Determinations for Oil and Gas Industries (Jan. 12, 2007), EPA docket EPA-HQ-OAR-2007-0629-0001.pdf.
- 31 *Id.*, p. 3.
- 32 *Id.*
- 33 *Id.*
- 34 *Id.*, p. 4.
- 35 See Memorandum from Gina McCarthy, Assistant Administrator, to Regional Administrators, Regions I - X, Withdrawal of Source Determinations for Oil and Gas Industries (Sept. 22, 2009), available at <http://www.epa.gov/region7/air/nsr/nsrmemos/oilgaswithdrawal.pdf>.
- 36 See Letter from Cheryl Newton, U.S. EPA, to Scott Huber, Summit Petroleum Corporation (Oct. 18, 2010), available at <http://www.epa.gov/region7/air/nsr/nsrmemos/singler5.pdf>.
- 37 *Id.*
- 38 *Id.*
- 39 *Id.*
- 40 690 F.3d at 735.
- 41 See 690 F.3d at 742.
- 42 690 F.3d at 743-44.
- 43 See 45 Fed. Reg. at 52,694.
- 44 690 F.3d at 748.
- 45 690 F.3d at 748-49.
- 46 45 Fed. Reg. at 52,695.
- 47 690 F.3d at 735.
- 48 690 F.3d at 751.
- 49 See 28 USC § 2101(c); Supreme Court Rule 13(3).
- 50 As one EPA official noted, there is “no evidence that any EPA office has ever attempted to indicate a specific distance for ‘adjacent’ on anything other than a case-by-case basis.” Letter from Richard Long, U.S. EPA, to Lynn Menlove, Utah Division of Air Quality (May 21, 1998), available at [www.epa.gov/region07/air/title5/t5memos/util-trl.pdf](http://www.epa.gov/region07/air/title5/t5memos/util-trl.pdf), citing to 45 Fed. Reg. 52,676, 52,695 (August 7, 1980) (“EPA is unable to say precisely at this point how far apart activities must be in order to be treated separately. The Agency can answer that question only through case-by-case determinations.”).
- 51 See Memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, “Applicability of the Summit Decision to EPA Title V and NSR Source Determinations,” available at <http://www.epa.gov/region07/air/title5/t5memos/inter2012.pdf>.
- 52 *Id.*
- 53 See U.S. EPA Region IV, “Georgia Environmental Protection Department Title V and New Source Review Program Review,” Jan. 20, 2005, p. 10, available at [http://www.epa.gov/region4/air/permits/programevaluations/GA\\_FinalReport.pdf](http://www.epa.gov/region4/air/permits/programevaluations/GA_FinalReport.pdf) (“If the separation distance between two facilities is greater than 20 miles, GAEPD considers the two facilities to be separate sources. For separation distances of less than 20 miles, a case-by-case single source determination is made. Regarding the single source determination criterion of same industrial grouping, GAEPD would consider the support relationship between two facilities as well as the SIC code of the facilities.”).
- 54 See, e.g., *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7 (D.C. Cir. 2012); *Texas v. EPA*, 690 F.3d 670 (5th Cir. 2012).

## 2013 Newsletter Editorial Board

*John C. Bottini, Editor*  
Georgia-Pacific LLC

*Catherine Nemetz Clutter*  
University of Georgia

*John Fortuna*  
King & Spalding LLP

*Kimberley Hale*  
Kazmarek, Geiger &  
Laseter LLP

*Jennifer A. Simon*  
Kazmarek, Geiger &  
Laseter LLP

*Karlie Clemons Webb*  
Troutman Sanders LLP

*Max Zygmunt*  
Mowrey Meezan  
Coddington  
Cloud LLP

## 2013 Environmental Law Section Officers

### CHAIR

Kasey Sturm  
Stack & Associates P.C.  
260 Peachtree Street,  
Suite 1200  
Atlanta, GA 30303  
Phone: (404) 525-9205  
[ksturm@stack-envirolaw.com](mailto:ksturm@stack-envirolaw.com)

### CHAIR-ELECT

John C. Bottini  
Georgia-Pacific LLC  
133 Peachtree Street NE,  
43rd Floor  
Atlanta, GA 30303  
Phone: (404) 652-4883  
[john.bottini@gapac.com](mailto:john.bottini@gapac.com)

### SECRETARY

Christopher “Max” Zygmunt  
Mowrey Meezan Coddington  
Cloud LLP  
1100 Peachtree St.  
Suite 650  
Atlanta, GA 30309  
Phone: (404) 969-0747  
[max.zygmunt@m2c2law.com](mailto:max.zygmunt@m2c2law.com)

### TREASURER

Richard A. Horder  
Kazmarek Geiger &  
Laseter LLP  
3490 Piedmont Road NE,  
Ste. 350  
Atlanta, GA 30305  
Phone: (404) 812-0843  
[rhorder@kglattorneys.com](mailto:rhorder@kglattorneys.com)

### MEMBER-AT-LARGE:

Katie Sheehan  
University of Georgia,  
School of Ecology  
River Basin Center  
110 Riverbend Rd, Rm 101  
Athens, GA 30602  
Phone: (706) 583-0463  
[katiesheehan80@gmail.com](mailto:katiesheehan80@gmail.com)

### IMMEDIATE PAST CHAIR

Mack McGuffey  
Troutman Sanders LLP  
600 Peachtree Street, N.E.,  
Suite 5200  
Atlanta, GA 30308-2216  
Phone: (404) 885-3698  
[mack.mcguffey@troutman-sanders.com](mailto:mack.mcguffey@troutman-sanders.com)



# OSAH Reporter

By John C. Bottini, Georgia-Pacific LLC

## Coastal Marshlands Protection Act Permitting

*Center for a Sustainable Coast, et al. v. Coastal Marshlands Protection Committee*, Docket No. OSAH-BNR-CM-1235369-63-Miller

On Dec. 10, 2012, Administrative Law Judge Kristin L. Miller reversed the Coastal Marshland Protection Committee's (CMPC) issuance of the Coastal Marshlands Protection Act (CMPA) permit for the construction of a new community marina along the Bull River in Chatham County. The permit applicant, Bull River Bluff Properties, LLC (Applicant), proposed the new marina to serve its adjacent condominium complex. As permitted, the marina would impact .38 acres of coastal marshlands. Petitioners Center for a Sustainable Coast, Ogeechee Riverkeeper and Savannah Riverkeeper challenged the issuance of the permit, alleging that the CMPC had issued the permit without requiring the Applicant to submit a "needs assessment."

The Applicant submitted several analyses of the market and alternatives, but Miller concluded that neither analysis constituted the needs assessment required by the CMPA and its implementing regulations. Miller held that a needs assessment "must include information sufficient to demonstrate that the applicant's need for a marina cannot be fulfilled through the use of existing public facilities." While the Applicant had provided a survey of existing public facilities in the vicinity, Miller noted that the survey failed to document the number of slip vacancies at local marinas or whether the Applicant's condominium residents currently used slips at existing facilities. In particular, Miller concluded that Applicant's analyses failed to demonstrate why the Bull River Marina, a public facility located 418 feet away from the proposed site, could not meet the needs of the complex's residents. Based on the record before the court, Miller held that the CMPC did not have sufficient information to conclude that "an unfulfilled need for additional slips exists." She therefore ruled that the CMPC had failed to meet the requirement for a needs assessment, granted summary determination for Petitioners, and reversed the CMPC's decision to issue the permit.

## Buffer Variances under Georgia's Erosion and Sedimentation Act

*Georgia Rivers Network and American Rivers v. Judson H. Turner*, Docket No. OSAH-BNR-EPD-ES-1308374-60-Miller

On July 6, 2012, the Director of Georgia's Environmental Protection Division issued a buffer variance under the Erosion and Sedimentation Act allowing the disturbance of nine miles of streams to accommodate construction of the 960-acre Tired Creek Fishing Lake in Grady County. Petitioners Georgia Rivers Network and American Rivers appealed the Director's

decision on the grounds that EPD failed to issue (or even consider) a buffer variance for 129 acres of wetlands that would also be affected. In a Jan. 14, 2013, decision, Hon. Kristin L. Miller ruled on a number of pending motions, including granting Petitioners' motion for summary determination and reversing the EPD Director's issuance of the buffer variance.

Initially, Grady County, the buffer variance applicant, moved to dismiss the Petition alleging that Petitioners lacked standing. The County argued that the Petitioners' injuries were caused by the federal Clean Water Act Section 404 permit that had been issued by the U.S. Army Corps of Engineers for the fishing lake project, and not by the buffer variance that the federal permit required the County to obtain from EPD. Grady County alleged that the Petitioners' injuries therefore could not be redressed in the present proceeding. Miller disagreed and found that the EPD Director's grant of the buffer variance was, in fact, a source of Petitioners' injuries. Furthermore, because the project could not proceed under the terms of the federal permit without the buffer variance, Miller concluded that Petitioners' injuries could be redressed by an order invalidating the variance. Accordingly, Miller held that Petitioners had met the requirements for associational standing and denied Grady County's motion to dismiss.

The parties' cross motions for summary determination presented the question of whether the requirement to obtain a buffer variance applies to wetlands. As background, the Erosion and Sedimentation Act establishes a 25-foot buffer "along the banks of all state waters, as measured horizontally from the point where vegetation has been wrested by normal stream flow or wave action..." O.C.G.A. § 12-7-6(b)(15) (A). In this case, it was undisputed that the EPD Director had not considered disturbances to wetlands in his buffer variance determination due to the agency's belief that wetlands do not require a buffer on account of a lack of "wrested vegetation." Miller concluded that nothing in the statute or legislative history supported such an exemption from the buffer requirement for wetlands. Miller reasoned that the statute's reference to the "point where vegetation has been wrested" does not limit the buffer requirement, but rather supplies a means of measuring the requisite buffer width. Miller's conclusion was further supported by the absence of a wetlands exemption to the buffer requirement among the six specific exemptions set forth in the statute. Miller declined to afford any deference to EPD's interpretation of the statute, in part because the agency had previously applied the Erosion and Sedimentation Act to require a buffer along coastal wetlands. For these reasons, Miller granted Petitioners' motion for summary determination and reversed the EPD Director's issuance of the buffer variance for the Tired Creek Fishing Lake.

# Pharmaceutical Waste Regulation: Fitting a Square Peg in a Round Hole

By John Johnson, Greg Blount, Karlie Clemons Webb, Hahnah Williams, Troutman Sanders LLP

With alarming headlines in recent years concerning the presence of drugs in our drinking water, pharmaceutical waste management has received heightened attention from regulators. There has been a significant increase in the number of on-site inspections, notices of violation and enforcement actions. The State of California alone has assessed substantial civil penalties against major, national retailers for alleged hazardous waste violations, including alleged mismanagement of pharmaceutical waste. In the wake of this heightened scrutiny, the regulated community (including, for example, big box retailers, hospitals, medical clinics, and retail pharmacies) is rigorously working to maintain regulatory compliance, but the applicable regulatory scheme has proven to be the source of much confusion.

Much of the confusion stems from the fact that the current regulatory scheme is ill-suited to pharmaceutical waste management. In acknowledging this fact, in 2008, EPA proposed to add pharmaceuticals to the list of Universal Wastes,<sup>1</sup> which, at least to the extent adopted by states, would have provided a streamlined process for management of those pharmaceuticals that are “hazardous” when discarded under the federal Resource Conservation and Recovery Act (RCRA). After being stalled for several years, the proposed rule was officially withdrawn in 2012. Thus, currently, entities that manage pharmaceuticals regulated as RCRA hazardous waste must conform their waste management practices to the existing RCRA regulations. The challenge of doing so is great, and becomes even greater in those instances where an entity has multiple facilities in differing regulatory jurisdictions. As described below, states often differ significantly in program requirements and complexity, as well as in the level of enforcement activity.

## Determining Whether a Pharmaceutical is a Hazardous Waste

Under the current RCRA regulatory scheme, a pharmaceutical becomes a waste when the pharmaceutical is discarded or intended to be discarded.<sup>2</sup> Once it is determined that a pharmaceutical is a “waste” and thus “pharmaceutical waste,” a determination must be made as to whether the pharmaceutical waste is RCRA hazardous. The first step in determining whether a pharmaceutical “waste” is hazardous under RCRA is to assess whether the pharmaceutical waste is classified as RCRA “listed” or “characteristic” hazardous waste by answering the following two questions: (1) Does the pharmaceutical have a sole

active ingredient that is listed on RCRA’s P-list (acute) or U-list (toxic)?<sup>3</sup> And (2) does the pharmaceutical exhibit one or more of the RCRA hazardous waste characteristics (ignitability, corrosivity, reactivity, and toxicity)?<sup>4</sup>

If the answer to either question is “yes,” with the exception of a few exclusions established in the RCRA regulations or in EPA guidance documents, the pharmaceutical waste must be managed as RCRA hazardous waste. Of course, as discussed below, state requirements may differ significantly from the federal program, including classifying certain pharmaceutical wastes as hazardous waste that are not regulated as RCRA hazardous waste.

These first two steps alone can be quite challenging for a pharmaceutical waste generator. A generator is responsible for fully understanding the active ingredients and hazardous waste characteristics for each of the pharmaceuticals that it stocks, which can be a daunting task given the number and variety of pharmaceuticals that are manufactured and the fact that pharmaceuticals may have several different names for drugs with the same active ingredient.

## Determining Which RCRA Regulations are Applicable

Once an entity determines that it generates pharmaceutical waste that must be managed as RCRA hazardous waste, the entity must then comply with an array of RCRA generator requirements, which relate to packaging, storing, labeling, transportation, and disposal. The stringency of the requirements varies depending on whether the generator is a Large Quantity Generator (LQG), Small Quantity Generator (SQG), or Conditionally Exempt Small Quantity Generator (CESQG). LQGs are required to comply with the full range of RCRA waste management requirements, while SQGs are subject to fewer requirements.<sup>5</sup> CESQGs are not subject to RCRA requirements, except for being able to verify that the facility is truly a CESQG based on the volume of hazardous waste generated.<sup>6</sup> As noted, states’ requirements can vary significantly from the federal requirements, and, in those circumstances, generators are required to comply with state-specific generator categories and requirements.

Under federal RCRA requirements, a generator is a LQG if it generates 2,200 pounds or more of hazardous waste (including pharmaceutical and non-pharmaceutical hazardous waste) in a calendar month or generates more than 2.2 pounds of acute (P-listed) hazardous waste in a calendar month.<sup>7</sup> A generator is considered a SQG if it generates

more than 220 pounds of hazardous waste but less than 2,200 pounds of hazardous waste per calendar month and no more than 2.2 pounds of acute hazardous waste per calendar month.<sup>8</sup> A generator is considered a CESQG if it generates less than 220 pounds of hazardous waste in a calendar month and less than 2.2 pounds of acute hazardous waste in a calendar month.<sup>9</sup>

Generally healthcare facilities, such as hospitals, clinics, and retail pharmacies, generate a small amount of hazardous waste. However, because a generator is automatically a LQG if it generates more than 2.2 pounds of acute hazardous waste in a calendar month or accumulates more than 2.2 pounds of acute hazardous waste at any time, many healthcare facilities can become LQGs because they generate more than 2.2 pounds of P-listed acute hazardous waste, such as Nicotine patches or Warfarin, a commonly used blood thinner. Such facilities must then operate in accordance with the full spectrum of RCRA hazardous waste requirements.

## Regulatory Confusion and Need for Change

Many issues related to management of pharmaceutical waste are a source of confusion for the regulated community (and, in a number of cases, the regulators). One major issue – which can determine the difference between LQG and SQG or CESQG generator status – concerns the regulatory status of containers that previously contained P-listed hazardous waste. Historically, it was unclear whether the weight of the containers should be counted when determining whether a generator exceeded 2.2 pounds of acute hazardous waste. In a November 2011 guidance document, titled *Containers that Once Held P-Listed Pharmaceuticals*, EPA verified that “it is only the *residue* in the non-RCRA-empty container that is considered a P-listed hazardous waste; the container itself is not a hazardous waste” and, “[a]ccordingly, it is only the weight of the *residue* in the container that needs to be counted toward generator status; the weight of the *container* does not need to be counted toward generator status.”<sup>10</sup> EPA noted that this guidance might enable facilities to be classified as SQGs or CESQGs that otherwise would have been classified as LQGs because of the containers’ weight that would push them over the 2.2 pounds of acute hazardous waste threshold.<sup>11</sup> While EPA’s guidance provides clarity at the federal level, since states are free to adopt more stringent regulations than federal requirements, they may choose to regulate containers holding P-listed residue as hazardous waste. Additionally, those facilities generating other types of P-listed hazardous waste may not benefit from the EPA clarification, as such other P-listed waste (e.g., Nicotine) combined with Warfarin and Warfarin residue, even excluding the containers, may often push the generator above the 2.2 pounds of acute hazardous waste.

## State-Specific Requirements

Much of the difficulty in pharmaceuticals waste management results from the fact that pharmaceuticals may be subject to different management standards in each state. A few of the varying state approaches are highlighted here, but they certainly are not all-inclusive. Each of the states has a federally-authorized hazardous waste program, with the exception of Alaska and Iowa, and while RCRA requires that state programs be at least as stringent as federal requirements, states are free to adopt regulations that are more restrictive than the federal program. While many state programs closely resemble the federal RCRA requirements, a number of state programs significantly differ from the federal program and from each other, presenting a challenge for healthcare providers. These regulatory inconsistencies make it particularly difficult for entities with facilities in multiple states to adopt a uniform hazardous waste program that can be implemented nationwide.

One common challenge is that states often regulate wastes as hazardous that are not regulated as hazardous under the federal RCRA program. Rhode Island, for example, has created “Rhode Island Wastes,” which are regulated as hazardous in Rhode Island but not under the federal RCRA program.<sup>12</sup> Oregon, Connecticut, and Vermont have created similar state-only designations. States have also varied from the federal RCRA program in other ways. For example, California regulates pharmaceutical waste that is a RCRA hazardous waste largely consistent with federal requirements, and, under the California Medical Waste Management Act (MWRA), regulates all other pharmaceutical waste as “biohazardous waste,” a subset of medical waste. Other examples include Minnesota’s addition of lethality to the list of hazardous waste characteristics and Washington’s classification of certain waste as “dangerous waste.”<sup>13</sup>

Two states, Florida and Michigan, have adopted universal waste rules specific to pharmaceutical waste management. Such universal waste rules provide benefits that are not provided currently under federal RCRA requirements or other states’ hazardous waste programs. For example, generators of hazardous pharmaceutical waste are able to store pharmaceutical waste for longer periods of time than is allowed under RCRA, and the waste is not counted toward generator status.<sup>14</sup> While seemingly advantageous, the rules only apply to pharmaceutical waste management within those states. Thus, when the pharmaceutical waste is transported outside of those states, it must be managed in accordance with the requirements of the states in which it is transported and disposed.

## Reverse Distribution of Pharmaceuticals

A major issue for healthcare providers concerns the regulatory status of pharmaceuticals managed through reverse distribution, which is the process by which healthcare



providers return non-dispensable pharmaceuticals to a third party reverse distributor. The reverse distributor determines whether the items are eligible to receive this monetary credit from the manufacturer, which can be substantial, and then determines whether and how the pharmaceuticals will be disposed or returned to the manufacturer or manufacturer's representative.

EPA (as well as other federal agencies) oversees aspects of pharmaceuticals reverse distribution (e.g., reverse distributors who dispose of hazardous pharmaceutical waste are RCRA generators), but the hazardous waste regulations directly address the regulatory status of the pharmaceuticals prior to the point at which they are discarded by the reverse distributor. EPA historically took the position that pharmaceuticals returned via the reverse distribution system do not become a "waste" until a determination by the reverse distributor is made to dispose of the item, provided there was a reasonable expectation that the pharmaceuticals would be recycled (e.g., reused, reclaimed, or sold overseas).<sup>15</sup> More recently, in the preamble to its 2008 proposed pharmaceuticals universal waste rule, EPA took the position that unused or expired pharmaceuticals that are being returned for possible manufacturer credit still have potential value and thus are not "waste."<sup>16</sup>

But like other areas of pharmaceutical waste management, some states have adopted different policies with regard to reverse distribution of pharmaceuticals, and other states' positions on the issue are unclear. The Minnesota Pollution Control Agency (MPCA), for example, in its *Program Management Decision (PMD) Memo*, dated May 2011, requires generators to meet certain very specific documentation requirements in order to manage pharmaceuticals through the reverse distribution process without having to comply with the full RCRA management standards for those pharmaceuticals.<sup>17</sup> The PMD Memo ultimately requires that a facility consider a pharmaceutical to be a "waste" at the healthcare facility level once it is determined that the pharmaceutical cannot be used for its intended purpose (e.g., an expired pharmaceutical would not be used for its intended purpose). The guidance document to the PMD Memo states, "In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste," and a generator must "[a]ssume a waste pharmaceutical is hazardous unless you have evaluated it and have documentation showing it to be nonhazardous."<sup>18</sup> Among others, the PMD requirements include providing documentation that all pharmaceuticals have either "not been evaluated" to determine whether they are hazardous waste or those that "would be hazardous waste in Minnesota will be disposed of according to hazardous waste disposal requirements."<sup>19</sup> Required documentation includes an agreement between the reverse distributor and generator establishing that pharmaceuticals will be disposed in accordance with hazardous waste disposal requirements and a management plan from the reverse distributor that indicates specific locations where pharmaceuticals will ultimately be disposed.<sup>20</sup>

## DEA Take-Back Proposed Rule

Another growing issue is pharmaceutical take-back programs, in which pharmaceuticals are brought to a designated location, such as a community drop-off location affiliated with a local fire department for subsequent disposal. While EPA implements RCRA, the U.S. Drug Enforcement Agency (DEA) also has authority to regulate pharmaceuticals that are designated as controlled substances, and thus entities who manage those pharmaceuticals must also comply with all applicable DEA requirements. On Dec. 21, 2012, the DEA proposed a new rule, "Disposal of Controlled Substances," noting that the "DEA found that in order to properly address the disposal of controlled substances by ultimate users, it was necessary to conduct a comprehensive review of DEA policies and regulations related to each element of the disposal process."<sup>21</sup> The DEA included in its review ultimate users of substances and others, including, for example, reverse distributors, which DEA recognized as "pertinent to the process of registrant disposal."<sup>22</sup> The proposed rule would expand the entities to whom users may lawfully "transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected."<sup>23</sup> DEA emphasizes that the rule would be completely voluntary for both consumers and the entities providing the take-back services.

The proposal does not specifically lay out how the DEA rule would work in conjunction with federal hazardous waste regulations under RCRA, but the rule does indicate that all otherwise applicable laws and regulations are applicable. Accordingly, if the final rule encourages the establishment



of take-back programs by the RCRA-regulated entities, an additional layer of complexity could be added to those entities' pharmaceutical waste management programs.

## What is Next in Pharmaceutical Waste Regulation?

The current lack of a federal regulatory scheme specific to pharmaceutical waste management is a continuing source of confusion for regulators and the regulated community alike. Although EPA's proposed rulemaking effort in 2008 to establish a more uniform program for pharmaceutical waste was ultimately withdrawn last year, the withdrawal was certainly not as a result of a lack of need for such a uniform program. Particularly at a time of heightened enforcement, the regulated community and regulators alike would benefit from a regulatory scheme that is more straightforward, streamlined and specific to pharmaceutical waste management.

Fortunately, it is clear that EPA appreciates the difficulties inherent in the current pharmaceutical waste regulatory framework, and despite its withdrawal of the proposed universal pharmaceutical waste rule, EPA has not ceased its effort to establish a regulatory framework that is better suited to pharmaceutical waste.

EPA notes on its website that the Agency anticipates releasing a new proposed pharmaceutical waste management rule for public comment in August 2013.<sup>24</sup> Currently it appears that EPA will not continue to pursue the universal waste route that the Agency proposed in 2008. Rather, it is likely that EPA will propose to pursue management standards unique to pharmaceutical waste. It is unclear whether the rule, if adopted, will be applicable in all states automatically, or whether states will have to adopt the rule in order for the rule to apply in the state, as would have been required had the proposed universal waste scheme been adopted. What is clear, however, is that moving forward, state regulators and the regulated community alike would benefit from a program specific to pharmaceutical waste management that will streamline the process. Such a regulatory scheme should address the multiple issues that are currently a source of confusion, and incorporate a regulatory acknowledgement of the reverse distribution process that is missing under the existing RCRA framework. Such a regulatory scheme would also ideally address take-back programs from EPA's perspective, given that DEA has now proposed regulations specific to such programs. Should EPA not ultimately adopt a rule specific to pharmaceuticals, it is likely that the states will continue to fill the void by adopting their own regulations specific to pharmaceuticals, raising further barriers to a more uniform and streamlined pharmaceutical waste management system.

### (Endnotes)

- 1 See 73 Fed. Reg. 73,520 (Dec. 2, 2008).
- 2 73 Fed. Reg. at 73,522.
- 3 40 C.F.R. § 261.33.
- 4 40 C.F.R. Part 261 Subpart C.
- 5 See 40 C.F.R. § 262.34(d)(5).
- 6 40 C.F.R. § 261.5(f) - (g).
- 7 73 Fed. Reg. at 73,522.
- 8 40 C.F.R. § 261.7(b)(1); 73 Fed. Reg. at 73,522.
- 9 40 C.F.R. § 261.5(a).
- 10 U.S. Environmental Protection Agency, *Containers that Once Held P-Listed Pharmaceuticals*, Nov. 4, 2011, at 2.
- 11 *Id.* at 3.
- 12 See <http://www.dem.ri.gov/pubs/regs/regs/waste/hwregs07.pdf>
- 13 Minn. R. 7045.0131; Washington Admin. Code 173-303-070.
- 14 See Fla. Admin. Code Ann. r. 62-370.186 and Mich. Admin. Code r. 299.9228.
- 15 U.S. Environmental Protection Agency RCRA Online Letter from Alan S. Corson, U.S. EPA Chief Waste Characterization Branch to Steven C. Wittmer, Merck, Sharp, & Dohme, Faxback #11012, May 13, 1981; U.S. Environmental Protection Agency RCRA Online Letter from Sylvia K. Lowrance, U.S. EPA Director Office of Solid Waste to BFI Pharmaceutical, RO #11606, May 16, 1991.
- 16 73 Fed.Reg. at 73,526.
- 17 Minnesota Pollution Control Agency, Program Management Decision Memo, Establishing Allowed Management of Undispensed Discarded Pharmaceuticals, May 6, 2011; Minnesota Pollution Control Agency, Reverse Distribution of Pharmaceuticals, Guidance for Minnesota Healthcare Providers, June 2011, available at <http://www.pca.state.mn.us/index.php/view-document.html?gid=4004>.
- 18 MPCA, Guidance for Minnesota Healthcare Providers.
- 19 *Id.*
- 20 *Id.*
- 21 77 Fed. Reg. 75,784, 75,784 (Dec. 21, 2012).
- 22 *Id.*
- 23 *Id.*
- 24 <http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm>. It is our understanding that there may be some slippage in the scheduling but that the proposed rule should be issued by the final quarter of 2013.

Save the Date  
The Environmental Law  
Section Summer Seminar,  
July 26-27, 2013,  
Omni Amelia Island  
Plantation, Amelia Island,  
Fla. Details will be available  
soon at [icelga.org](http://icelga.org).

# What a Long, Strange Trip It's Been...The Final Air Toxics Standards for Major and Area Source Boilers Are Here

By Mark Wenclawiak, CCM, Susie Bowden, Chuck Doyno, & Colin McCall, All4, Inc.

In late December 2012, the U.S. Environmental Protection Agency (U.S. EPA) Administrator signed final versions of what are commonly known as the Major Source Boiler MACT and the Area Source Boiler MACT (the National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Industrial/Commercial/Institutional Boilers and Process Heaters – Major Sources (40 CFR Part 63, Subpart DDDDD) and for Industrial, Commercial, and Institutional Boilers – Area Sources (40 CFR Part 63, Subpart JJJJJJ), respectively). The final versions of these rules are amendments to the versions promulgated in March 2011.

The Major Source Boiler MACT was published in the Federal Register on Jan. 31, 2013 and is effective April 1, 2013.<sup>1</sup> The Area Source Boiler MACT was published on Feb. 1, 2013 and became effective immediately.<sup>2</sup> Therefore, the compliance clock for affected facilities is running. Given the time necessary to prepare engineering studies for control device options, to conduct testing programs, and to prepare and submit permit applications, the three year timeframe for compliance with the Major Source Boiler MACT now may be a challenge for some facilities. With the Area Source Boiler MACT, the schedule for compliance is even tighter. Though the rules have provisions for a one year extension, the message is clear: now is the time for action.

## Introduction

The journey of the Boiler MACT began over 10 years ago. Following many legal challenges and multiple interim versions, the final rules are now in place and interested parties (regulated facilities, attorneys, and environmental professionals) must again spend time to learn their nuances. Though the ultimate framework of the rules has not changed drastically over the years (the rules have always included emission standards and initial and continuous compliance, notification, reporting, and recordkeeping requirements), the “what, how, and when” of the requirements have been in flux. This article provides an overview of both the Major Source and Area Source Boiler MACT standards as promulgated, including the schedule for important milestones.

## Who's In?

As a refresher, applicability of either Boiler MACT standard is based on a facility's (not an individual boiler's) aggregate potential emission rates of hazardous air pollutants (HAPs).

Potential emissions are those created by assuming an emission source operates 24 hours per day, 365 days per year (unless a federally enforceable operating limitation or emission restriction is in place). Those facilities that emit, or have the potential to emit, at least 10 tons per year (tpy) of one HAP, or at least 25 tpy of a combination of HAPs, are major sources subject to the Major Source Boiler MACT. Otherwise, a facility is an area (minor) source subject to the Area Source Boiler MACT.

U.S. EPA estimates that there are approximately 1.5 million boilers in the United States. Of these, about 1.3 million boilers will be considered “clean” sources and will not be covered by either rule. Regarding the remaining approximately 200,000 boilers:

- About 2,300 (less than 1 percent of all U.S. boilers) will be subject to specific emission standards under one of the MACT standards. These boilers are typically located at major industrial complexes such as pulp and paper mills and chemical manufacturers.
- Approximately 197,000 boilers (approximately 13 percent of all U.S. boilers) will be subject to work practice standards such as periodic tune-ups to minimize emissions of HAPs.

## Major Source Boiler MACT

The Major Source Boiler MACT establishes 19 subcategories of boilers based on the design of the combustion equipment (e.g., the fuel type and the type of boiler system) and classifications of “new” versus “existing.” New sources are those that commenced construction or reconstruction after June 4, 2010. Otherwise, a source is classified as an existing source.

## Emission limits

For most of the 19 subcategories, the final rule establishes numerical limits for the following five pollutants: carbon monoxide (CO), hydrogen chloride (HCl), mercury (Hg), and filterable particulate matter (PM) or total selected metals (TSM). The emission limits only apply to units 10 million British thermal units per hour (MMBtu/hr) or greater heat input. Gas fired units or small (less than 10 MMBtu/hr heat input) boilers are subject only to work practice standards. All of the subcategories are subject to periodic tune-up work practices for dioxin/furan emissions.



Of particular interest to many affected facilities, the final rule establishes an alternative emission standard for CO to address process variability. The alternative standard allows the use of a facility's continuous emission monitoring system (CEMS) and is based on either a 30-day or 10-day rolling average depending on the subcategory.

The final rule maintained output-based emission limits as an option for sources, which may encourage and facilitate more cost-effective, long-term pollution prevention through process efficiency.

The emissions and operating limits apply at all times the unit is in operation except for periods of "startup" and "shutdown." In lieu of limits, the Major Source Boiler MACT provides work practice standards for these periods.

### Compliance demonstration requirements

The compliance demonstration requirements consist of emissions testing, parametric monitoring (rather than emissions monitoring), fuel analysis, and work practice standards.

Initial compliance with all applicable emission limits must be demonstrated through performance testing for new and existing boilers, and, generally, performance tests are required annually. However, if a facility's performance tests for a given pollutant for at least two consecutive years show that the emissions are at or below 75 percent of the applicable emission limit, and there are no changes in the operation of the individual boiler or air pollution control equipment that could increase emissions, the facility may choose to conduct performance tests for the pollutant every third year.

The rule ensures continuous compliance through parametric monitoring based on the applicable operating limit or work practice standard (e.g., scrubber pressure drop and liquid flow rate). In what is considered a major win for industry, the final rule removed a requirement for units combusting biomass with heat input capacities of 250 MMBtu/hr or greater to use CEMS for measuring PM emissions. Depending on the size and fuel of an affected boiler, other alternative testing and monitoring methods are available for a facility.

The final rule also requires the development and implementation of a site-specific fuel monitoring plan. A fuel analysis is required for each type of fuel burned in the boiler, unless the unit does not burn more than one type of fuel, in which case a fuel analysis is not required. Similarly, when natural gas, refinery gas, or certain other gas fuels are co-fired with other fuels, conducting a fuel analysis is not required. The frequency of on-going sampling depends on the sampling results (i.e., reduced sampling is required if the results are less than prescribed thresholds).

All boilers, regardless of the subcategory, are subject to periodic tune-up work practices for dioxin/furan emissions. The frequency of tune-ups depends on the classification of the

boiler (new versus existing), the fuels used, and the rated heat input of the boiler.

In addition, existing sources must complete a one-time energy assessment of affected boilers (not the entire facility). The energy assessment must be conducted by a qualified energy assessor (as defined in the rule) and the scope of the assessment must include specific criteria listed in the rule.

### Compliance Deadlines

Existing sources must be in compliance by Jan. 31, 2016, (three years from Federal Register publication). New sources must be in compliance by Jan. 31, 2013 or upon startup, whichever is later. Under certain circumstances, U.S. EPA is allowing facilities to apply for a one (1) year extension if such time is needed for the installation of controls. The agency that issued a facility's permit holds the authority to approve an extension.

Additionally, an initial notification submittal is due by May 31, 2013. A Notification of Compliance Status (NOCS) report must be submitted within 60 days of completing all applicable performance tests and/or other initial compliance demonstrations. Facilities will be required to submit reports (notifications, test reports, etc.) electronically using the Compliance and Emissions Data Reporting Interface (CEDRI), which will increase the public scrutiny of a facility's compliance status.

### Area Source Boiler MACT

The subcategories covered by the final Area Source Boiler MACT are:

- Coal;
- Biomass;
- Oil;
- Seasonal boilers – boilers that do not operate for at least seven (7) consecutive months for each 12-month period and that fire only oil or biomass;
- Small oil-fired boilers – boilers with a heat input capacity of less than or equal to five (5) MMBtu/hr;
- Boilers with an oxygen trim system – boilers that operate a continuous oxygen trim system and maintain an optimum air-to-fuel ratio; and
- Limited-use boilers – boilers that fire solid or liquid fuels with an average annual capacity factor less than or equal to 10 percent.

The final rule also excludes certain boilers from the source categories above and, therefore, from the Area Source Boiler MACT altogether. These additional excluded boilers include electric boilers, residential boilers, temporary boilers, certain RCRA-permitted boilers, and certain boilers used as emission control devices.

## Emission limits

Under the Area Source Boiler MACT, only (1) new coal, biomass, or oil-fired boilers with a rated heat input capacity of at least 10 MMBtu/hr and (2) existing coal-fired boilers with a rated heat input capacity of at least 10 MMBtu/hr are subject to numerical emission limits. Otherwise, affected boilers are only subject to work practice standards.

## Work practice standards

The final rule also contains work practice and management practice requirements. For the four new subcategories added at the final rule stage (seasonal boilers, small oil-fired boilers, boilers with oxygen trim systems, and limited-use boilers), tune-up requirements apply, but they are only required every five years. For other boilers, biennial tune-ups are required. Generally, tune-ups must be conducted within 30 days of startup, and the final rule does not require tune-ups for new or reconstructed boilers.

As under the Major Source Boiler MACT, the Area Source Boiler MACT requires a one-time energy assessment performed by a qualified energy assessor for existing coal-fired, biomass-fired, or oil-fired boilers with heat input capacity of 10 MMBtu/hr and greater.

## Initial compliance demonstrations & deadlines

Sources subject to an emission limit demonstrate compliance through performance tests. Whereas sources subject to only work practice standards must comply with the prescribed schedule for continuous compliance demonstration purposes, including any applicable tune-up requirements.

Similar to the Major Source Boiler MACT, the Area Source Boiler MACT classifies boilers as “new” or “existing” based on the date June 4, 2010. Existing boilers must be in compliance by March 21, 2014, and an initial notification for those boilers is due by Jan. 20, 2014. Existing boilers not subject to emission limits must also *demonstrate* compliance by March 21, 2014, and notice to EPA that the source completed its initial tune-up is due by July 19, 2014. In contrast, existing boilers subject to limits must demonstrate compliance through a performance test by Nov. 17, 2014.

New sources, generally speaking, must be in compliance upon startup. And those new sources subject to emission limits must conduct a performance test by the later of Nov. 17, 2014 or 180 days after startup.

As with the Major Source Boiler MACT, extensions to the compliance dates of up to one year may be granted by the appropriate Title V permitting authority if such time is needed for the installation of controls.

## Where to Start?

Affected facilities must determine (or re-confirm) which subcategories are applicable to their combustion sources, and subsequently determine the suite of applicable emission limits and requirements. Facilities undoubtedly have a lot of work ahead of them to demonstrate compliance with all of the initial performance testing, required tune-ups and energy assessment recordkeeping, and installation of add-on control devices, if necessary. In many cases, modifications to existing boilers will require permitting, which alone can take years. Therefore, now is the time to prepare a compliance strategy. Some specific considerations follow:

- **Capital Costs:** Many facilities have struggled to set plans for future expansion amidst the uncertainty of how much capital expenditure Boiler MACT compliance will require. Now the costs of compliance can be defined, but that process isn't always simple because, for example, controlling certain pollutants such as CO could increase emissions of other pollutants such as nitrogen oxides (NO<sub>x</sub>), resulting in the potential applicability of New Source Review (NSR) permitting regulations. Understanding how these rules play together is now critical.
- **Resource Access:** Many facilities will be required to install new PM emissions controls or upgrade existing controls. These installations and upgrades will be resource intensive. They will require access to the equipment, to engineering resources, and to stack testing firms. Once again, the earlier these resource issues are addressed, the better.
- **Construction Permitting Timelines:** Almost all modifications to comply with Boiler MACT will require some level of Clean Air Act construction permitting. Most states require permit applications for control devices and air system modifications. Like any other construction permitting process, receiving the appropriate permits authorizing installation and construction of control devices will take time. Further, there are some facilities that have limited windows of time (shutdowns, ramp downs in production, etc.) during which these projects can be implemented. When state permitting timelines are overlaid with the available windows to complete the physical changes, the Area Source Boiler MACT March 21, 2014, compliance date and the Major Source Boiler MACT Jan. 31, 2016, compliance date do not seem so far away.

### (Endnotes)

- 1 78 Fed. Reg. 7138 (Jan. 31, 2013).
- 2 78 Fed. Reg. 7488 (Feb. 1, 2013).