South Carolina Board of Health and Environmental Control

Agenda
April 5, 2017

Call to Order – 10:00 a.m., Board Room (#3420)
South Carolina Department of Health and Environmental Control
2600 Bull Street, Columbia, S.C.

1. Minutes of March 9 meeting

2. Placement of Dronabinol (Syndros) Into Schedule II SC Controlled Substances.

3. Final Review Conference – Docket No. 17-RFR-12, Keenan Energy Group f/k/a Keenan Oil Co.

Executive Session (if needed)

Adjournment

Note: The April 13 meeting of the S.C. Board of Health and Environmental Control has been cancelled. The next scheduled meeting will be May 11.

BOARD OF HEALTH AND ENVIRONMENTAL CONTROL
Summary Sheet
April 5, 2017

__X__ Action
____ Information

I. SUBJECT: Placement of Dronabinol (Syndros) into Schedule II for Controlled Substances

II. FACTS: Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled "Manner in which changes in schedule of controlled substances shall be made." Pursuant to this section, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule II substances are listed in Section 44-53-210. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate substance as a controlled substance if the federal government has so designated.
Section 44-53-160(C) states:

> If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(-)-delta-9-transtetrahydrocannabinol (delta-9-THC)] oral solution. Thereafter, the Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a scheduling recommendation that would result in Syndros (and other oral solutions containing dronabinol) being placed in schedule II of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing FDA-approved products of oral solutions containing dronabinol in schedule II of the CSA. DATES: The effective date of this rulemaking is March 23, 2017. https://www.gpo.gov/fdsys/pkg/FR-2017-03-23/pdf/2017-05809.pdf.

Federal Authority

Under the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), which was signed into law on November 25, 2015, DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the FDA. As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply:

(1) The Secretary of HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system, and that it appears that such drug has an abuse potential and
(2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b).

In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days. The law further states that the 90-day timeframe starts the later of:

(1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation or
(2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause therefor.

Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.

Subsection (j) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Background

Syndros is an oral solution that contains 5 mg of dronabinol (delta-9- THC) per mL of solution. Dronabinol is the generic name (International Nonproprietary Name, INN) for the (-) delta-9-trans isomer of tetrahydrocannabinol (THC), the primary psychoactive substance in marijuana. On June 1, 2015, Insys Therapeutics (Sponsor) submitted an NDA to the U.S. Food and Drug Administration (FDA) for Syndros, an oral formulation of dronabinol. The FDA accepted the NDA filing for Syndros on August 6, 2015 and approved the NDA on July 5, 2016. On December 28, 2016, the DEA received notification that HHS/FDA approved Syndros for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS), and for the treatment of nausea and vomiting resulting from cancer chemotherapy in patients who failed to respond to conventional antiemetic therapies.

Determination To Schedule FDA Approved Products Containing Dronabinol in an Oral Solution

On December 28, 2016, the HHS provided the DEA with a scientific and medical evaluation and scheduling recommendation related to dronabinol. Because DEA's authority to issue this interim final rule under subsection 811(j) is limited to drugs that are the subject of an approved NDA, and because the NDA was limited to an oral solution containing dronabinol, DEA's discussion here of the scheduling criteria is likewise limited to oral solutions containing dronabinol in FDA approved drug products.

2. HHS's scientific and medical evaluation contained an eight-factor analysis of the abuse potential of FDA-approved products of oral solutions containing dronabinol and recommended that such products be placed in schedule II of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that FDA-approved dronabinol oral solutions met the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA. Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule FDA approved dronabinol oral solution as a schedule II controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its scheduling action:

Eight-Factor Analysis

1. *Its Actual or Relative Potential for Abuse*: Dronabinol is a generic name for the (-) delta-9-trans isomer of tetrahydrocannabinol (THC). THC is the primary psychoactive substance in marijuana. Dronabinol is the active pharmaceutical ingredient in Syndros. As stated by HHS, Marinol (synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule) was approved by the FDA for medical use on May 31, 1985 and placed in schedule II based on its accepted medical use and high abuse potential. On July 2, 1999, Marinol was rescheduled from schedule II to schedule III because of the findings of the DEA that the difficulty of separating dronabinol from the sesame oil formulation and the delayed onset of behavioral effects due to oral route administration supported a lower abuse potential of Marinol as compared to substances in Schedule II.

HHS indicated that the formulation of Syndros (oral solution) is easier to abuse than Marinol because this liquid formulation can be manipulated to produce concentrated extracts of dronabinol for abuse by inhalation (smoking or vaping) or through other routes of administration. Because of the large amount of dronabinol in Syndros oral solution it has a greater potential for extraction than Marinol and thus has a greater abuse potential. Syndros oral solution can be easily manipulated to other forms that can be easily abused through inhalation and oral routes of administration. The 2014 and 2015 Monitoring the Future (MTF) 3 survey indicated that THC containing products are being taken orally, smoked, and vaporized using devices such as e-cigarettes. There is a lack of evidence pertaining to diversion of Syndros or Marinol from

legitimate drug channels. Syndros is not yet available on the market. Marinol and generic forms that reference it, have low levels of abuse and diversion according to the HHS and DEA, and this is attributed to the formulation of dronabinol in sesame oil.

2. *Scientific Evidence of Its Pharmacological Effects, if Known*: Dronabinol, also known as THC, is the primary psychoactive substance in marijuana and is also the active pharmaceutical ingredient in Syndros and Marinol. Some behavioral and other effects of dronabinol in humans consist of dizziness, nausea, tachycardia, euphoria, enhanced sensory perception, heightened imagination, impaired judgment, emotional lability, and increased appetite. Discriminative stimulus effects of dronabinol are specific to CB1 cannabinoids, and unique because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not generalize to dronabinol.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance*: Dronabinol is the generic name for (-)delta-9-transtetrahydrocannabinol (THC) and is chemically known as (-)-(6aR-trans)- 6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3- pentyl-6H-dibenzo[b,d]pyran-1-ol and has the chemical formula C21H30O2. It was found that Syndros oral solution and Marinol capsules differ in their physiochemical properties. Specifically, Syndros, unlike Marinol, can be manipulated such that the dronabinol can be evaporated into residues that can be reconstituted for smoking or abused intravenously. According to HHS, Syndros contains a large amount of dronabinol (150 mg of dronabinol in 30 mL of solution) and would be an easily accessible source for abuse via the oral route.

4. *Its History and Current Pattern of Abuse*: There is a long history of abuse of THC in the United States. HHS noted that dronabinol in Marinol capsules is difficult to extract and therefore, cannot be used for smoking, vaping, or as an edible. The dronabinol in Syndros, however, is relatively easy to extract and concentrated forms can be used for smoking, vaping, or the sweetened alcoholic dronabinol in Syndros can be used as a substitute for THC in edibles. In the 2015 MTF survey, it was reported that teens were more likely to use ecigarettes (vaping) than regular cigarettes (smoking). In this survey, 6.1 percent of 12th graders reported vaporizing marijuana or hash oil in their last e-cigarette. Additionally, in a recent analysis of marijuana users, 12 percent of users preferred vaping the drug over any other method and considered it a safer alternative to smoking. As a result, these data suggest that if dronabinol extracts or concentrates are available from dronabinol sources such as Syndros, a certain percent of the population are likely to vape these substances.

5. *The Scope, Duration, and Significance of Abuse*: As noted by HHS, information on the scope, duration, and significance of abuse of dronabinol was considered for both oral and inhalation routes. Data analyzed from the 2014 Summer Styles Survey, a national representative consumer panel survey of adult marijuana users aged 18 or older, showed that the majority of current marijuana users prefer smoking marijuana. In the same survey, it was reported that 16 percent of the current users consumed THC containing edibles or drinks. Individuals who preferred vaping (using a device to vaporize liquid THC) believed that vaping is ''healthier, better tasting'' and resulted in ''better effects'' associated with marijuana and THC.

6. *What, if any, Risk There is to the Public Health*: As stated by HHS, labeling on the Marinol packaging indicates that Central Nervous System (CNS) adverse reactions are dose-related and subject to patient variability. CNS adverse reactions are more likely to occur at higher doses of dronabinol. Following oral Marinol (dronabinol) doses of 0.4 mg/kg, CNS symptoms such as amnesia, confusion, delusions, depression, and hallucinations have been observed. According to HHS, it is assumed that Syndros oral solution will have similar adverse effects to Marinol. One concern with Syndros is that there is a large amount of dronabinol present in the product (150 mg dronabinol per bottle, 30 mL solution) that can easily be abused orally and may result in unintended overdoses. Oral consumption of dronabinol, compared to inhaled THC, may result in psychoactive effects that are delayed and stronger with an increased risk of experiencing serious adverse events. When dronabinol (THC) is smoked, the drug rapidly reaches the brain and psychoactive effects are felt within minutes of inhalation, which allows the subject to control the dose more readily. Due to the absorption and metabolism by the liver following oral ingestion of dronabinol, it takes longer for an individual to feel the psychoactive effects. Therefore, the individual may underestimate the ingestion amount needed to feel the psychoactive effects

7. *Its Psychic or Physiological Dependence Liability*: As stated in labeling for Marinol and Syndros, psychological and physical dependence has been observed in healthy individuals following use of dronabinol. Abrupt discontinuation of dronabinol in individuals receiving 210 mg/day (25 times the recommended daily dose for the treatment of anorexia associated with weight loss in AIDS patients) for 12 to 16 days resulted in undesirable symptoms including insomnia, irritability, and restlessness at 12 hours after discontinuation. These symptoms worsened to include hot flashes, anorexia, sweating, rhinorrhea, loose stools, and hiccoughs at 24 hours after discontinuation of dronabinol.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA*: Dronabinol oral solution is not an immediate precursor of any controlled substance.

Conclusion

After considering the scientific and medical evaluation conducted by the HHS, the HHS' recommendation, and its own eight-factor analysis, the DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of dronabinol oral solution. As such, the DEA hereby schedules FDA-approved products containing dronabinol oral solution as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular Schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1. FDA-approved products containing dronabinol in an oral solution have a high potential for abuse. The physicochemical properties of Syndros allow extraction of dronabinol for abuse through oral or inhalation (smoking or vaping) routes. Dronabinol is not easily extractable from Marinol. Oral abuse of dronabinol-containing products is associated with hallucinations, mood alterations, and paranoia. The 2015 MTF Survey reported that 6.1 percent of the 12th graders used e-cigarettes to vaporize marijuana or cannabinoid substances. Similarly, the 2014 Summer Styles Survey, 16 percent of current marijuana users indicated that they have consumed dronabinol containing edibles or drinks. These data collectively indicate FDA-approved oral solutions containing dronabinol have high potential for abuse.

2. FDA-approved products containing dronabinol in an oral solution have a currently accepted medical use in treatment in the United States. The FDA approved an oral solution containing dronabinol (Syndros) for the treatment of anorexia associated with weight loss in patients with AIDS, and for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

3. FDA-approved products containing dronabinol in an oral solution may lead to severe physical dependence. Following discontinuation of dronabinol at a dose 210 mg/day (25 times higher than the recommended daily dose for anorexia associated with weight loss in AIDS patients) for 12 to 16 consecutive days, withdrawal symptoms including irritability, insomnia, and restlessness were observed at 12 hours after discontinuation. These withdrawal symptoms worsened to include hot flashes, sweating, rhinorrhea, loose stools, hiccoughs, and anorexia at 24 hours after discontinuation of dronabinol. The withdrawal symptoms decreased gradually over the next 48 hours and patients reported having disturbed sleep for several weeks after discontinuation of dronabinol.

Based on these findings, the Acting Administrator of the DEA concludes that FDA-approved products containing dronabinol [(-)-delta-9-trans tetrahydrocannabinol (delta-9-THC)] in an oral solution warrant control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

RECOMMENDATION: Department staff recommend the Board place dronabinol [(-)-delta-9-trans tetrahydrocannabinol (delta-9-THC)] in an oral solution, also known by the brand name Syndros, into Scheduled II of the SC Controlled Substances Act, effective immediately.

Lisa Thomson, Bureau Chief
Bureau of Drug Control

Shelly Kelly, Deputy Director
Health Regulations

March 29, 2017

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–344]

Schedules of Controlled Substances: Placement of FDA-Approved Products of Oral Solutions Containing Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule, with request for comments.

SUMMARY: On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(-)-delta-9-*trans*-tetrahydrocannabinol (delta-9-THC)] oral solution. Thereafter, the Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a scheduling recommendation that would result in Syndros (and other oral solutions containing dronabinol) being placed in schedule II of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing FDA-approved products of oral solutions containing dronabinol in schedule II of the CSA.

DATES: The effective date of this rulemaking is March 23, 2017. Interested persons may file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before April 24, 2017. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before April 24, 2017.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–344" on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, VA 22152.
- *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Acting Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–8953.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services and Drug Enforcement Administration eight-factor analyses, to this interim final rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing, Notice of Appearance at Hearing, or Waiver of Participation in Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. In accordance with 21 CFR 1308.44(a) through (c), requests for a hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule

issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Requests for a hearing and notices of participation must conform to the requirements of 21 CFR 1308.44(a) or (b), as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver of an opportunity for a hearing must conform to the requirements of 21 CFR 1308.44(c) including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing are restricted to "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *." Requests for a hearing and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

Under the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), which was signed into law on November 25, 2015, DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the FDA. As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system, and that it appears that such drug has an abuse potential and (2) the Secretary recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days.

The law further states that the 90-day timeframe starts the later of (1) the date DEA receives the HHS scientific and medical evaluation/scheduling recommendation or (2) the date DEA receives notice of the NDA approval by HHS. In addition, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause therefor. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of subsections 21 U.S.C. 811(b), (c), and (d) and 21 U.S.C. 812(b).

Background

Syndros is an oral solution that contains 5 mg of dronabinol (delta-9-THC) per mL of solution. Dronabinol is the generic name (International Nonproprietary Name, INN) for the (-) delta-9-trans isomer of tetrahydrocannabinol (THC), the primary psychoactive substance in marijuana. On June 1, 2015, Insys Therapeutics (Sponsor) submitted an NDA to the U.S. Food and Drug Administration (FDA) for Syndros, an oral formulation of dronabinol. The FDA accepted the NDA filing for Syndros on August 6, 2015 and approved the NDA on July 5, 2016. On December 28, 2016, the DEA received notification that HHS/FDA approved Syndros for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS), and for the treatment of nausea and vomiting resulting from cancer chemotherapy in patients who failed to respond to conventional anti-emetic therapies.

Determination To Schedule FDA-Approved Products Containing Dronabinol in an Oral Solution

On December 28, 2016, the HHS provided the DEA with a scientific and medical evaluation and scheduling recommendation related to dronabinol. Because DEA's authority to issue this interim final rule under subsection 811(j) is limited to drugs that are the subject of an approved NDA, and because the NDA was limited to an oral solution containing dronabinol, DEA's discussion here of the scheduling criteria is likewise limited to oral solutions containing dronabinol in FDA-approved drug products.[2] HHS's scientific and medical evaluation contained an eight-factor analysis of the abuse potential of FDA-approved products of oral solutions containing dronabinol and recommended that such products be placed in schedule II of the CSA.

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that FDA-approved dronabinol oral solutions met the 21 U.S.C. 812(b)(2) criteria for placement in schedule II of the CSA.

Pursuant to subsection 811(j), and based on the HHS recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule FDA-approved dronabinol oral solution as a schedule II controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in its scheduling action. Please note that both the DEA and HHS analyses are available in their entirety under "Supporting Documents" in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number "DEA–344." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. *Its Actual or Relative Potential for Abuse:* Dronabinol is a generic name for the (-) delta-9-*trans* isomer of tetrahydrocannabinol (THC). THC is the primary psychoactive substance in marijuana. Dronabinol is the active pharmaceutical ingredient in Syndros. As stated by HHS, Marinol (synthetic dronabinol in sesame oil and encapsulated in a soft gelatin capsule) was approved by the FDA for medical use on May 31, 1985 and placed in schedule II based on its accepted medical use and high abuse potential. On July 2, 1999, Marinol was rescheduled from schedule II to schedule III because of the findings of the DEA that the difficulty of separating dronabinol from the sesame oil formulation and the delayed onset of behavioral effects due to oral route administration supported a lower abuse potential of Marinol as compared to substances in Schedule II. 64 FR 35928.

According to HHS, although Syndros oral solution and Marinol capsules have

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

[2] To the extent HHS's submissions to DEA are outside the scope of this interim final rule (*i.e.,* those addressing dronabinol beyond that contained in an FDA-approved oral solution), they will not be addressed in this document.

the same pharmacology, these formulations differ in their physical and chemical properties. Both these formulations have abuse potential as demonstrated by their effects on subjective scores of "Drug Liking" in human abuse potential studies. HHS indicated that the formulation of Syndros (oral solution) is easier to abuse than Marinol because this liquid formulation can be manipulated to produce concentrated extracts of dronabinol for abuse by inhalation (smoking or vaping) or through other routes of administration. Because of the large amount of dronabinol in Syndros oral solution it has a greater potential for extraction than Marinol and thus has a greater abuse potential. Based on the data from in vitro studies conducted by the Sponsor, the large amount of dronabinol in the Syndros formulation, its pharmacokinetics upon oral administration, and its contribution to marijuana psychoactivity, HHS stated that the abuse potential of the dronabinol oral solution is similar to that of other THC containing products such as concentrates, infused edibles and drinks. Similar to these THC containing products, Syndros oral solution can be easily manipulated to other forms that can be easily abused through inhalation and oral routes of administration.

The 2014 and 2015 Monitoring the Future (MTF) [3] survey indicated that THC containing products are being taken orally, smoked, and vaporized using devices such as e-cigarettes. There is a lack of evidence pertaining to diversion of Syndros or Marinol from legitimate drug channels. Syndros is not yet available on the market. Marinol and generic forms that reference it, have low levels of abuse and diversion according to the HHS and DEA, and this is attributed to the formulation of dronabinol in sesame oil.

2. *Scientific Evidence of Its Pharmacological Effects, if Known:* Dronabinol, also known as THC, is the primary psychoactive substance in marijuana and is also the active pharmaceutical ingredient in Syndros and Marinol. Dronabinol binds to and activates the cannabinoid receptors (CB1 and CB2). HHS states that CB1 receptors activation underlie the psychotropic effects and many other pharmacological effects of dronabinol. Some behavioral and other effects of dronabinol in humans consist of dizziness, nausea, tachycardia, euphoria, enhanced sensory perception, heightened imagination, impaired judgment, emotional lability, and increased appetite. Dronabinol has been reported to be self-administered intravenously by squirrel monkeys and intracerebroventricularly by rats. Discriminative stimulus effects of dronabinol are specific to CB1 cannabinoids, and unique because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not generalize to dronabinol.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Dronabinol is the generic name for (-)delta-9-*trans*-tetrahydrocannabinol (THC) and is chemically known as (-)-(6a*R*-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[*b,d*]pyran-1-ol and has the chemical formula $C_{21}H_{30}O_2$. At room temperature (25 °C), dronabinol is a light-yellow oil and hardens upon refrigeration (4 °C) and is insoluble in water. The FDA-approved Syndros formulation consists of 5 mg dronabinol/mL of a 50 percent w/w alcoholic solution. Syndros will be marketed as 30 mL aliquots in clear, amber glass bottles and each bottle will contain 150 mg dronabinol.

In vitro manipulation studies with Syndros and Marinol (positive control) were conducted by the Sponsor. It was found that Syndros oral solution and Marinol capsules differ in their physiochemical properties. Specifically, Syndros, unlike Marinol, can be manipulated such that the dronabinol can be evaporated into residues that can be reconstituted for smoking or abused intravenously. According to HHS, Syndros contains a large amount of dronabinol (150 mg of dronabinol in 30 mL of solution) and would be an easily accessible source for abuse via the oral route.

4. *Its History and Current Pattern of Abuse:* There is a long history of abuse of THC in the United States. HHS noted that dronabinol in Marinol capsules is difficult to extract and therefore, cannot be used for smoking, vaping, or as an edible. The dronabinol in Syndros, however, is relatively easy to extract and concentrated forms can be used for smoking, vaping, or the sweetened alcoholic dronabinol in Syndros can be used as a substitute for THC in edibles. In the 2015 MTF survey, it was reported that teens were more likely to use e-cigarettes (vaping) than regular cigarettes (smoking). In this survey, 6.1 percent of 12th graders reported vaporizing marijuana or hash oil in their last e-cigarette. Additionally, in a recent analysis of marijuana users, 12 percent of users preferred vaping the drug over any other method and considered it a safer alternative to smoking. As a result, these data suggest that if dronabinol extracts or concentrates are available from dronabinol sources such as Syndros, a certain percent of the population are likely to vape these substances.

5. *The Scope, Duration, and Significance of Abuse:* As noted by HHS, information on the scope, duration, and significance of abuse of dronabinol was considered for both oral and inhalation routes. Data analyzed from the 2014 Summer Styles Survey, a national representative consumer panel survey of adult marijuana users aged 18 or older, showed that the majority of current marijuana users prefer smoking marijuana. In the same survey, it was reported that 16 percent of the current users consumed THC containing edibles or drinks. Individuals who preferred vaping (using a device to vaporize liquid THC) believed that vaping is "healthier, better tasting" and resulted in "better effects" associated with marijuana and THC.

6. *What, if any, Risk There is to the Public Health:* As stated by HHS, labeling on the Marinol packaging indicates that Central Nervous System (CNS) adverse reactions are dose-related and subject to patient variability. CNS adverse reactions are more likely to occur at higher doses of dronabinol. Following oral Marinol (dronabinol) doses of 0.4 mg/kg, CNS symptoms such as amnesia, confusion, delusions, depression, and hallucinations have been observed. According to HHS, it is assumed that Syndros oral solution will have similar adverse effects to Marinol. One concern with Syndros is that there is a large amount of dronabinol present in the product (150 mg dronabinol per bottle, 30 mL solution) that can easily be abused orally and may result in unintended overdoses.

Oral consumption of dronabinol, compared to inhaled THC, may result in psychoactive effects that are delayed and stronger with an increased risk of experiencing serious adverse events. When dronabinol (THC) is smoked, the drug rapidly reaches the brain and psychoactive effects are felt within minutes of inhalation, which allows the subject to control the dose more readily. Due to the absorption and metabolism by the liver following oral ingestion of dronabinol, it takes longer for an individual to feel the psychoactive effects. Therefore, the individual may underestimate the ingestion amount needed to feel the psychoactive effects

[3] MTF is a research program conducted at the University of Michigan's Institute for Social Research, under grants from NIDA. MTF tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades and high school graduates into adulthood by conducting national surveys.

which may potentially result in an overdose.

7. *Its Psychic or Physiological Dependence Liability:* As stated in labeling for Marinol and Syndros, psychological and physical dependence has been observed in healthy individuals following use of dronabinol. Abrupt discontinuation of dronabinol in individuals receiving 210 mg/day (25 times the recommended daily dose for the treatment of anorexia associated with weight loss in AIDS patients) for 12 to 16 days resulted in undesirable symptoms including insomnia, irritability, and restlessness at 12 hours after discontinuation. These symptoms worsened to include hot flashes, anorexia, sweating, rhinorrhea, loose stools, and hiccoughs at 24 hours after discontinuation of dronabinol.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA:* Dronabinol oral solution is not an immediate precursor of any controlled substance.

Conclusion: After considering the scientific and medical evaluation conducted by the HHS, the HHS' recommendation, and its own eight-factor analysis, the DEA has determined that these facts and all relevant data constitute substantial evidence of a potential for abuse of dronabinol oral solution. As such, the DEA hereby schedules FDA-approved products containing dronabinol oral solution as controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular Schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(2), finds that:

1. FDA-approved products containing dronabinol in an oral solution have a high potential for abuse. The physicochemical properties of Syndros allow extraction of dronabinol for abuse through oral or inhalation (smoking or vaping) routes. Dronabinol is not easily extractable from Marinol. Oral abuse of dronabinol-containing products is associated with hallucinations, mood alterations, and paranoia. The 2015 MTF Survey reported that 6.1 percent of the 12th graders used e-cigarettes to vaporize marijuana or cannabinoid substances. Similarly, the 2014 Summer Styles Survey, 16 percent of current marijuana users indicated that they have consumed dronabinol containing edibles or drinks. These data collectively indicate FDA-approved oral solutions containing dronabinol have high potential for abuse.

2. FDA-approved products containing dronabinol in an oral solution have a currently accepted medical use in treatment in the United States. The FDA approved an oral solution containing dronabinol (Syndros) for the treatment of anorexia associated with weight loss in patients with AIDS, and for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

3. FDA-approved products containing dronabinol in an oral solution may lead to severe physical dependence. Following discontinuation of dronabinol at a dose 210 mg/day (25 times higher than the recommended daily dose for anorexia associated with weight loss in AIDS patients) for 12 to 16 consecutive days, withdrawal symptoms including irritability, insomnia, and restlessness were observed at 12 hours after discontinuation. These withdrawal symptoms worsened to include hot flashes, sweating, rhinorrhea, loose stools, hiccoughs, and anorexia at 24 hours after discontinuation of dronabinol. The withdrawal symptoms decreased gradually over the next 48 hours and patients reported having disturbed sleep for several weeks after discontinuation of dronabinol.

Based on these findings, the Acting Administrator of the DEA concludes that FDA-approved products containing dronabinol [(-)-delta-9-trans tetrahydrocannabinol (delta-9-THC)] in an oral solution warrant control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

Requirements for Handling FDA-Approved Products Containing Dronabinol in an Oral Solution.

Preliminarily, it should be noted that any form of dronabinol other than in an FDA-approved drug product remains a schedule I controlled substance, and those who handle such material remain subject to the regulatory controls, and administrative, civil, and criminal sanctions, applicable to schedule I controlled substances set forth in the CSA and DEA regulations. However, for those who handle dronabinol oral solution exclusively in the form of an FDA-approved drug product, the following is a summary of the schedule II regulatory requirements that apply as a result of this interim final rule:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) FDA-approved products containing dronabinol in an oral solution, or who desires to handle such products, must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles FDA-approved products containing dronabinol in an oral solution, and is not registered with the DEA, must submit an application for registration and may not continue to handle such products, unless the DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Quota.* Only registered manufacturers are permitted to manufacture FDA-approved products containing dronabinol in an oral solution in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

3. *Disposal of stocks.* Upon obtaining a schedule II registration to handle FDA-approved products containing dronabinol in an oral solution, any person who does not desire or is not able to maintain such registration must surrender all quantities of such products, or may transfer all quantities of such products to a person registered with the DEA in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

4. *Security.* FDA-approved products containing dronabinol in an oral solution are subject to schedule II security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and in accordance with 21 CFR 1301.71–1301.93.

5. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

6. *Inventory.* Every DEA registrant who possesses any quantity of FDA-approved products containing dronabinol in an oral solution must take an inventory of such products on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with the DEA to handle FDA-approved products containing dronabinol in an oral solution must take an initial inventory of all stocks of controlled

substances (including FDA-approved products containing dronabinol in an oral solution) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including FDA-approved products containing dronabinol in an oral solution) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for FDA-approved products containing dronabinol in an oral solution, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Orders for FDA-approved products containing dronabinol* in an oral solution. Every DEA registrant who distributes FDA-approved products containing dronabinol in an oral solution is required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

9. *Prescriptions.* All prescriptions for FDA-approved products containing dronabinol in an oral solution must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

10. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule II controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of FDA-approved products containing dronabinol in an oral solution may only be for the legitimate purposes authorized by the FDCA and CSA.

11. *Importation and Exportation.* All importation and exportation of FDA-approved products containing dronabinol in an oral solution must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

12. *Liability.* Any activity involving FDA-approved products containing dronabinol in an oral solution not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

As explained above, under 21 U.S.C. 811(j), where a new drug is (1) approved by the Department of Health and Human Services (HHS) and (2) HHS recommends control in CSA schedule II–V, the DEA is required to issue an interim final rule scheduling the drug within 90 days. Additionally, the law specifies that the rulemaking shall become immediately effective as an interim final rule without requiring the DEA to demonstrate good cause. Therefore, the standard notice-and-comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action.

Executive Orders 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(j), this scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 603(a), "[w]henever an agency is required by [5 U.S.C. 553], or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretive rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis." As noted in the above discussion regarding applicability of the Administrative Procedure Act, the notice-and-comment requirements of section 553 of the APA, 5 U.S.C. 553, do not apply to this scheduling action. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, the DEA has determined that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on

competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. In § 1308.12, add paragraph (f)(2) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(f) * * *

(2) Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration	(7365)

* * * * *

Dated: March 20, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–05809 Filed 3–22–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0100]

Drawbridge Operation Regulation; Des Allemands Bayou, Des Allemands, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Burlington Northern Santa Fe Railroad swing span drawbridge across Des Allemands Bayou, mile 14.0, at Des Allemands, St. Charles and Lafourche Parishes, Louisiana. The deviation is necessary to install two open-deck spans for increased reliability of bridge operations. This deviation allows the bridge to remain in the closed-to-navigation position for two (2) separate, two-day periods.

DATES: This deviation is effective from 6 a.m. on April 20, 2017 through 12 noon on April 28, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0100] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Giselle MacDonald, Bridge Management Specialist, Coast Guard; telephone 504–671–2128, email *Giselle.T.MacDonald@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Burlington Northern Santa Fe Railroad Company requested a temporary deviation from the operating schedule for the swing span drawbridge across Des Allemands Bayou, mile 14.0, at Des Allemands, St. Charles and Lafourche Parishes, Louisiana. The deviation was requested to install two open-deck spans, one on each side of the existing swing span, to increase the reliability of bridge opening and closing operations.

The draw currently operates under 33 CFR 117.440(b). The draw of the Burlington Northern Santa Fe Railroad Bridge, Mile 14.0, shall open on signal Monday through Friday from 7 a.m. to 3 p.m. At all other times the draw shall open on signal if at least 4 hours notice is given.

For purposes of this deviation, the bridge will remain closed to navigation for two separate dates, 30 hours each, from 6 a.m. April 20, 2017 through 12 noon, April 21, 2017 and from 6 a.m., April 27, 2017 through 12 noon, April 28, 2017. During this deviation, vessels will not be allowed to pass through the bridge. The bridge has a vertical clearance of 3 feet above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, fishing vessels and recreational craft.

The Coast Guard will inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 17, 2017.

Eric A. Washburn,

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2017–05810 Filed 3–22–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP73

Release of VA Records Relating to HIV

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its medical regulations governing the release of VA medical records. Specifically, VA is eliminating the restriction on sharing a negative test result for the human immunodeficiency virus (HIV) with veterans' outside providers. HIV testing is a common practice today in healthcare and the stigma of testing that may have been seen in the 1980s when HIV was first discovered is no longer prevalent. Continuing to protect negative HIV tests causes delays and an unnecessary burden on veterans when VA tries to share electronic medical information with the veterans' outside providers through electronic health information exchanges. For this same reason, VA will also eliminate restrictions on negative test results of sickle cell anemia. This final rule eliminates the current barriers to electronic medical information exchange.

DATES: This final rule is effective April 24, 2017.

South Carolina Board of Health and Environmental Control
Final Review Conference
April 5, 2017

Final Review Conference Docket No. 17-RFR-12, Keenan Oil Co.

Requests for Final Review were filed on February 8, 2017.

Parties and Counsel of Record
Keenan Energy Group f/k/a Keenan Oil Co.
represented by W. Thomas Lavender with Nexsen Pruet
South Carolina Department of Health and Environmental Control
Represented by Sara P. Bazemore, SCDHEC Office of General Counsel

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dhec
Healthy People. Healthy Communities.

January 24, 2017

Keenan Oil Co., Inc.
PO Box 3218
Columbia, SC 29230-3218

Re: **Underground Storage Tank (UST)** Permit – 07705
Green Electric Co., 2248 Sumter St., Columbia, SC
Report received – December 2, 2016

Dear Sir or Madam:

An assessment report received by the UST Management Division on December 2, 2016, indicates that groundwater collected from a temporary monitoring well at this location is contaminated with petroleum constituents. A file review indicates Keenan Oil Co., Inc. as the tank owner at the time of tank removal and therefore, the responsible party for the petroleum contamination documented in the Phase II assessment. The State Underground Petroleum Environmental Response Bank (SUPERB) Account provides financial assistance for the cleanup of a site contaminated by a release from a regulated UST system provided that the facility associated with the release meets certain eligibility criteria. The Division has determined that this release is eligible for cleanup using SUPERB funds. The responsible party must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds.

The SUPERB Act Section 44-2-130(E)(1) states: "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the Superb Account for site rehabilitation shall submit a written application to the department." For your convenience, a SUPERB Account Application/Statement of Insurance form is enclosed. Please complete and return the attached form. You must request access to the SUPERB Account in order for the Division to complete the SUPERB qualification process.

South Carolina UST Control Regulation 61-92, Section 280.93(a) and 280.113 of the South Carolina Underground Storage Tank Control Regulations requires that tank owners submit and maintain proof of financial responsibility (FR) until subsequent corrective action is complete.

Should you have any questions pertaining to this matter, please contact me at (803) 898-0647.

Respectfully,

Denise M. Place

Denise M. Place
Regulatory Compliance Section
UST Management Division
Bureau of Land and Waste Management

Enclosure

dhec

Superb Account Application
Ust Management Division

Pursuant to the State Underground Petroleum Environmental Response Bank (SUPERB) Act 44-2-130(E)(1): "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the SUPERB Account for site rehabilitation shall submit a written application to the department."

Permit #: _____ Facility Name: _____

Facility Address: _____

Owner Name: _____

Owner Address: _____

Owner Phone #: _____

For the following section, circle **YES** or **NO:**

YES or **NO** I request compensation from the SUPERB Account for the release discovered/reported on _____.

You/your company must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds (Pursuant to the SUBERB Act 44-2-130). According to department records, you/your company had _____ as your financial responsibility mechanism at the time the release was reported. If this information is inaccurate, please correct it by checking the appropriate mechanism below:

☐ **Letter of Credit** ☐ **Insurance Policy** ☐ **Self-Insurance** ☐ **Surety Bond** ☐ **Guarantee**

INSURANCE STATEMENT

This site is potentially eligible to receive state monies to assist in site rehabilitation. Before eligibility for the SUPERB funds can be determined, written confirmation of the existence or non-existence of an environmental insurance policy for this site is required. Please circle **YES** or **NO** with regard to the following:

Is there now, or has there ever been an insurance policy or other financial mechanism that covers this UST release?

YES or **NO**

My policy provider is _____

The policy number is _____

The policy deductible is _____ Policy limit: _____

If you have this type of insurance, please include a copy of the policy with this report.

Owner Signature: _____

Print Signatory Name: _____

Date: _____

Sworn before me this _____ day of _____, 20_____.

_____

Notary Public (Signature)

for the State of _____
(if other than South Carolina, affix seal)

NEXSEN|PRUET

W. Thomas Lavender, Jr.
Member
Admitted in SC

February 8, 2017

HAND DELIVERY

Ms. Lisa Lucas Longshore, Clerk
South Carolina Board of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Re: Keenan Energy Company f/k/a Keenan Oil Co., Inc.
Underground Storage Tank (UST) Permit – 07705
Green Electric Co., 2248 Sumter St., Columbia, SC

Dear Ms. Longshore:

We represent Keenan Energy Company f/k/a Keenan Oil Co., Inc. ("Keenan") in the above-referenced matter.

On November 7, 2008, this Board issued a Final Agency Decision in *In Re: Keenan Oil Company*, Board Docket No. 08-RFR-109 ("2008 Decision"). Attached as **Appendix A** is a copy of the 2008 Decision. In the 2008 Decision, the Board held that USTs which were removed prior to December 24, 1988, and reported to DHEC in a March 14, 1989 site report ("1989 Site Report") where not subject to a $25,000 deductible. Attached as **Appendix B** is a copy of the 1989 Site Report.

By letter dated January 24, 2017, the Bureau of Land and Waste Management ("Bureau") notified Keenan that its was responsible for a $25,000 deductible for a release from a UST removed prior to December 24, 1988 from the former Green Electric Co., 2248 Sumter St., Columbia, SC ("Green Electric Site") and reported to DHEC in the very same March 14, 1989 report referenced above. A copy of the January 24, 2017 letter to Keenan ("Staff Determination") is attached as **Appendix C**.

Keenan asserts that the Staff Determination is in **direct conflict** with the Board's decision in the 2008 Decision. Pursuant to S.C. CODE ANN. § 44-1-60, Keenan requests the DHEC Board's final review of the Staff Determination that cleanup of the Green Electric Site is subject to a $25,000 deductible prior to cleanup using

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Nexsen Pruet, LLC
Attorneys and Counselors at Law

SUPERB funds. Keenan requests that the Board conduct a final review of the Staff Determination and find that the Green Electric Site is subject to a **zero deductible** prior to cleanup using SUPERB funds. Our firm's check in the amount of $100 for the filing fee is enclosed.

While Keenan would assert that the reasons set forth above are sufficient for the Board to grant the request and reverse the Staff Determination, additional background is provided. SUPERB was originally enacted in 1988. (1988 S.C. Act No. 486). Prior to December 24, 1988, Keenan closed and removed the UST at the Green Electric Site in accordance with the 1988 statute and the applicable regulations. On March 14, 1989, Keenan provided the Department with a report on the closure and removal of a number of USTs, including the UST at the Green Electric Site. Section 44-2-110 of the 1988 Act, the statute in effect at the time of Keenan's removal of the UST, created an early detection incentive program ("amnesty"), which made "[a]ll sites involving releases from underground storage tanks reported to the department any time from midnight on December 31, 1987, to midnight on December 31, 1989 . . . qualified sites for the expenditure of funds from the SUPERB Account, provided that a written report is filed with respect thereto." (1988 S.C. Act No. 486). In other words, as long as the site was reported to the Department during the grace period, the site qualified for SUPERB funds regardless of when the release occurred. Under the original Section 44-2-130(A), a party reporting the site during the grace period was "eligible to directly bill or be reimbursed for all reasonable costs incurred in connection with site rehabilitation" up to one million dollars and was not responsible for any deductible. (1988 S.C. Act No. 486) (emphasis added). The 1990 amendment to Section 44-2-130(A) further emphasized that all reasonable costs could be recovered "[f]or sites reported during the grace period established under the early detection incentive program." (1990 S.C. Act no. 473). Since Keenan removed the UST at the Green Electric Site and reported the site during the grace period, Keenan is not responsible for any deductible associated with a release form the former UST, regardless of when that release was discovered.

Additionally, Keenan removed the UST at the Green Electric Site and made the required reporting to the Department in accordance with the regulations in effect at the time of the removal. On May 22, 1985, the South Carolina Underground Storage Tank Control Regulations were promulgated. These regulations were not updated until March 23, 1990, more than a year after Keenan's removal of the UST. Therefore, the 1985 regulations are the applicable regulations for the removal of the UST at the Green Electric Site. These 1985 regulations outlined the process of abandoning a UST by removing it from the ground in R.61-92.12.B and specified that the owner of any abandoned UST must notify the Department in accordance with the annual reporting requirements detailed in Section R.61-92.7.H. Under the 1985 South Carolina Underground Storage Tank Control Regulations, no further reporting or testing was necessary. The 1989 Site Report satisfied the reporting requirement of

R.61-92 concerning the UST removal to the Department during the grace period as affirmed by the 2008 Decision.

Although a 1995 amendment later shifted the focus from the reporting of the site to the reporting of the release, this amendment did not exist at the time Keenan acted in reliance upon the then current statute and closed the UST by removal. Under the law existing at the time of removal, Keenan, having reported the site to the Department, qualified to receive SUPERB funds to cover all reasonable costs incurred in connection with site rehabilitation, regardless of when the release occurred, and was not responsible for any deductible before receiving SUPERB funds. Having proactively removed the UST in 1988 in reliance upon the law then existing, Keenan is not responsible for a $25,000 deductible based on an amendment to statute that was made almost a year after the UST was removed.

Keenan asserts that the Bureau is bound by the 2008 Decision relying upon the identical factual basis. We appreciate the Board's consideration of this request for final review. If additional information or documentation is needed, please do not hesitate to contact me.

Sincerely,

W. Thomas Lavender, Jr.

Enclosures

cc: Keenan Energy Company

Appendix A

SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

FINAL AGENCY DECISION

In Re: Keenan Oil Company

Board Docket No. 08-RFR-109

Appearances: W. Tommy Lavender, Jr., Esquire for Keenan Oil Company, Inc, Requestor

Stephen P. Hightower, Esquire, for South Carolina Department of Health and Environmental Control

This matter comes before the South Carolina Board of Health and Environmental Control (Board) for final review pursuant to S.C. Code Ann. § 44-1-60. On August 27, 2008, Department staff issued letter determining that the Requestor was required to satisfy the twenty-five thousand dollar ($25,000.00) deductible for the petroleum release on property owned by Carolina Tractor and Equipment site located at 7011 Garners Ferry Road, Columbia, South Carolina (the "Site"). The Requestor filed a timely request for a final review conference and the conference was held on October 9, 2008.

Under the information presented at the conference, the Board has determined that the Requestor is not be required to pay the twenty-five thousand dollar ($25,000) deductible for this release. Accordingly, the Department staff decision of August 27, 2008 is reversed.

Paul C. Aughtry, III
Chairman
Board of Health and Environmental Control
For the Board

November 7, 2008

Notice of Right to Request Contested Case Hearing Before Administrative Law Court

S.C. Code §44-1-60(F)(2) provides that within thirty days after the receipt of the Board's written final agency decision an applicant, permittee, licensee, or affected person desiring to contest the final agency decision may request a contested case hearing before the Administrative Law Court, in accordance with the Administrative Procedures Act. A request for a contested case hearing before the Administrative Law Court (ALC) must be filed in accordance with the Rules of the ALC, including payment of the ALC's filing fee, at the following address:

Clerk's Office
South Carolina Administrative Law Court
Edgar A. Brown Building
1205 Pendleton St., Suite 224
Columbia, SC 29201

The ALC's Notice of Request for Contested Case Hearing form and the Rules of the ALC can be found at the ALC's website: http://www.scalc.net. If a party files a request for a contested case hearing with the ALC, the party must serve a copy of the request on DHEC and any other parties at the same time the request is filed with the ALC. A copy of the request for a contested case hearing must be delivered or mailed to DHEC at the following address:

Lisa L. Longshore
Clerk of the Board
SC DHEC
2600 Bull Street
Columbia, SC 29201

The above information on filing a request for a contested case hearing before the Administrative Law Court is provided as a courtesy; parties before the ALC are responsible for complying with all applicable requirements of the Court.

Appendix B

KEENAN OIL COMPANY, INC.
P. O. BOX 8218
COLUMBIA, S. C. 29230

OFFICE & PLANT
3020 W. BELTLINE
PHONE 252-0887

27RB

S.C. Department of Health and Envirnmental Control
Bureau of Finance
2600 Bull Street
Columbia, S.C. 29201

March 14, 1989

Re: Annual Registration Fee for UST

Per the South Carolina Underground Storage Tank Control regulations R.61-92-7, please receive the below list as notification of tanks no longer in operation. In each case the tanks have been removed and disposed of or have been scheduled for removal prior to December 24, 1988. In only one case the equipment has remained in the ground per the request of property owner.

Permit ID	Invoice Number	Total Fees
N-32-NO-06025 New South Supply	QI03210-2	60.00
N-32-NO-06015 New South Supply	QI03209-4	60.00
N-40-NO-09834 South Carolina Tractor	QI03222-7	60.00
N-40-NO-07927 South Carolina Tractor	QI03221-9	120.00
N-40-NO-07691 Walker Plumbing Co. (550 gal.	QI03230-0 tank filled with sand)	60.00
N-40-NO-07850 Smith Grading & Paving	QI03219-3	60.00
N-40-NO-07930 Robinson Holding Co.	QI03213-6	120.00
N-32-NO-06114 Bryant Heating Co.	QI03179-9	60.00
N-40-NO-07893 Fast Fare #821	QI03049-4	120.00
N-40-NO-07705 Green Electric	QI03196-3	60.00
N-40-NO-07926 Sox & Freeman	QI03223-5	120.00
N-40-NO-07693 Capital City Dodge	QI03181-5	60.00
N-40-NO-09908	QI03242-5	60.00

Capital City Dodge		
N-40-NO-07873 Hewitt Robins Company	QI03197-1	60.00
N-40-NO-07707 Kaminer Heating Co.	QI03203-7	60.00
N-32-NO-06136 John E. Fitts	QI03201-1	60.00
N-40-NO-07901 W.F. Ballentine	QI03228-4	60.00
N-40-NO-07690 Westside Ice & Fuel Co.	QI03232-6	60.00
N-40-NO-07877 Industrial Alignment	QI03199-7	60.00
N-40-NO-07810 Pulliam Motor Co.	QI03212-8	120.00
N-40-NO-07695 Sam Jones 66	QI03214-4	180.00
N-40-NO-07855 Goodlett Equipment Co. Inc.	QI03195-5	60.00
N-40-NO-07854 Alexander, Taylor & Murphy	QI03173-2	60.00
N-40-NO-07899 Air Products & Chemical	QI03172-4	60.00
N-32-NO-06115 Blanchard Machinery Co.	QI03176-5	180.00
N-40-NO-07904 Brawley's Service Station	QI03178-1	180.00
N-40-NO-07699 Campbell's 66	QI03180-7	360.00
N-40-NO-07931 E.D. Sauls	QI03187-2	60.00
N-40-NO-07903 Cricket Bait Shop	QI03186-4	120.00
N-40-NO-07928 SCE&G	QI03217-7	60.00
N-32-NO-06118	QI03225-0	360.00

Sunset 66

N-40-NO-07883 Keenan Oil Co.	QI03204-5	120.00
N-40-NO-07708 Palmetto Wholesale Co.	QI03211-0	60.00
N-40-NO-07882 Columbia Crawler Corp.	QI03184-9	180.00
N-40-NO-07706 Jones Garbage Service	QI03202-9	60.00
Kline Iron and Steel		***

Listed below are tanks billed in error:

N-40-NO-07766 McCrory Const. Co. (Keenan Oil does not own any tanks at this location)	QI03208-6	120.00
N-40-NO-07900 B&W Lumber Co. (Tank is owned by B&W and DHEC has billed them)	QI03174-0	60.00
N-40-NO-07692 Spring Valley Country Club (This is a heating Oil tank)	QI03224-3	60.00

Listed below are tanks once owned by Keenan Oil but have been sold (a copy of bill of sales is attached):

N-32-NO-06117 E.F. Aughtry 66	QI03188-0	120.00
N-40-NO-07896 Bert A. Brantley	QI03175-7	60.00
N-40-NO-07876 Lumber Builder & Supply	QI03206-0	60.00
N-40-NO-07898 William Boyles	QI03233-4	120.00
N-32-NO-06123 Wilson Construction Co.	QI03234-2	60.00

Please remove all the above equipment from the annual registration fee charge for reasons so outlined.

If there are any questions please don't hesitate calling.

Sincerely;

William J. Keenan, II.

Appendix C

dhec
Healthy People. Healthy Communities.

January 24, 2017

Keenan Oil Co., Inc.
PO Box 3218
Columbia, SC 29230-3218

Re: **Underground Storage Tank (UST)** Permit – 07705
Green Electric Co., 2248 Sumter St., Columbia, SC
Report received – December 2, 2016

Dear Sir or Madam:

An assessment report received by the UST Management Division on December 2, 2016, indicates that groundwater collected from a temporary monitoring well at this location is contaminated with petroleum constituents. A file review indicates Keenan Oil Co., Inc. as the tank owner at the time of tank removal and therefore, the responsible party for the petroleum contamination documented in the Phase II assessment. The State Underground Petroleum Environmental Response Bank (SUPERB) Account provides financial assistance for the cleanup of a site contaminated by a release from a regulated UST system provided that the facility associated with the release meets certain eligibility criteria. The Division has determined that this release is eligible for cleanup using SUPERB funds. The responsible party must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds.

The SUPERB Act Section 44-2-130(E)(1) states: "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the Superb Account for site rehabilitation shall submit a written application to the department." For your convenience, a SUPERB Account Application/Statement of Insurance form is enclosed. Please complete and return the attached form. You must request access to the SUPERB Account in order for the Division to complete the SUPERB qualification process.

South Carolina UST Control Regulation 61-92, Section 280.93(a) and 280.113 of the South Carolina Underground Storage Tank Control Regulations requires that tank owners submit and maintain proof of financial responsibility (FR) until subsequent corrective action is complete.

Should you have any questions pertaining to this matter, please contact me at (803) 898-0647.

Respectfully,

Denise M. Place

Denise M. Place
Regulatory Compliance Section
UST Management Division
Bureau of Land and Waste Management

Enclosure

dhec

Superb Account Application
Ust Management Division

Pursuant to the State Underground Petroleum Environmental Response Bank (SUPERB) Act 44-2-130(E)(1): "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the SUPERB Account for site rehabilitation shall submit a written application to the department."

Permit #: _____ Facility Name: _____

Facility Address: _____

Owner Name: _____

Owner Address: _____

Owner Phone #: _____

For the following section, circle **YES** or **NO:**

YES or NO I request compensation from the SUPERB Account for the release discovered/reported on _____.

You/your company must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds (Pursuant to the SUBERB Act 44-2-130). According to department records, you/your company had _____ as your financial responsibility mechanism at the time the release was reported. If this information is inaccurate, please correct it by checking the appropriate mechanism below:

☐ **Letter of Credit** ☐ **Insurance Policy** ☐ **Self-Insurance** ☐ **Surety Bond** ☐ **Guarantee**

INSURANCE STATEMENT

This site is potentially eligible to receive state monies to assist in site rehabilitation. Before eligibility for the SUPERB funds can be determined, written confirmation of the existence or non-existence of an environmental insurance policy for this site is required. Please circle **YES** or **NO** with regard to the following:

Is there now, or has there ever been an insurance policy or other financial mechanism that covers this UST release?

YES or NO

My policy provider is _____

The policy number is _____

The policy deductible is _____ Policy limit: _____

If you have this type of insurance, please include a copy of the policy with this report.

Owner Signature: _____

Print Signatory Name: _____

Date: _____

Sworn before me this _____ day

of _____, 20_____.

_____

Notary Public (Signature)

for the State of _____

(if other than South Carolina, affix seal)

SCHDEC, UST Management Division, 2600 Bull Street, Columbia, SC 29201, PHONE (803) 898-0589, FAX (803) 898-0673, www.scdhec.gov/ust

BEFORE THE SOUTH CAROLINA BOARD OF HEALTH AND ENVIRONMENTAL CONTROL

STAFF RESPONSE TO REQUEST FOR FINAL REVIEW
Docket No. 17-RFR-12

Requestor/Permittee: Keenan Energy Group, f/k/a Keenan Oil Co.,
UST Site ID #07705 (Green Electric Co., 2248 Sumter Street, Columbia, SC)

RE: Requirement of Payment of deductible before access to SUPERB funds.

I. SUMMARY

a) Type of Decision

This request for review challenges a January 24, 2017 decision by DHEC's Bureau of Land and Waste Management, Underground Storage Tank Management Division (Division or DHEC or Department) that Keenan Oil Co., Inc. must satisfy a deductible prior to using SUPERB funds.

Department records indicate that Keenan Oil Co., Inc. (Keenan Oil) was the owner of and removed one 1,000 gallon gasoline underground storage tank (UST) from the Green Electric Co. Site (Site) on or before December 24, 1988. Keenan Oil submitted a letter to the Department, dated March 14, 1989 (1989 Tank Fee Notification). Keenan Oil did not report any releases in its 1989 Tank Fee Notification. The notification from Keenan Oil listed several sites, including the Green Electric Site, with tanks no longer in operation. Division files do not indicate that a release was reported at the time the referenced UST was removed or at any time by Keenan Oil for this Site. Therefore, on January 24, 2017 the Division confirmed a release from the former gasoline UST located at the Green Electric Site.

The 1988 SUPERB Act offered an early detection incentive program, wherein a person who made a written report of a release during the statutory amnesty period would not be required to satisfy a deductible under SUPERB. Keenan Oil made reports for releases at other sites during the amnesty period, but did not report a release at the Green Electric Site.

As the tank owner at the time of tank removal, Keenan Oil is responsible for site rehabilitation of this release. The release is qualified for State Underground Petroleum Environmental Response Bank (SUPERB) funding however, since the release was not reported by June 30, 1993, Keenan Oil must satisfy a $25,000 deductible prior to accessing SUPERB funds toward cleanup of the release as set forth under the SUPERB Act.

b) Parties and Other Relevant Names

Requestor, Keenan Oil Co., Inc., owner of the underground storage tank formerly located at 2248 Sumter Street, Columbia, S.C.

ARM Environmental Services, Inc., contractor for another party unrelated to Keenan Oil, who was issued a permit on November 8, 2016 to install three temporary monitoring wells on

the property at 2248 Sumter Street, Columbia, S.C., which resulted in the detection of a petroleum release at the Green Electric Site.

c) Location: UST Site ID# 07705, Green Electric Co., 2248 Sumter Street, Columbia, S.C.

d) Relevant Chronology

May 2, 1988 –

- In 1988, South Carolina enacted the State Underground Petroleum Environmental Response Bank (SUPERB) Act, S.C. Code § 44-2-10 et seq. The 1988 SUPERB Act established an incentive program "to encourage early detection, reporting, and cleanup of releases from leaking petroleum storage tanks." S.C. Code § 44-2-110 (1988).

March 14, 1989 –

- 1989 Tank Fee Notification. Keenan Oil submitted a letter to the Department reporting the removal of USTs from a list of sites, including the Green Electric Site. Keenan Oil did not report any releases in this letter.

June 30, 1993 –

- Amnesty Period Ends (midnight deadline to make a written report of a release to the Department. The end date for the amnesty period was extended several times, but finally ended at midnight on June 30, 1993. See 1992 Act No. 501, Part II, Section 43F).

December 2, 2016 –

- The Division received a phase II assessment report that indicated the existence of a petroleum release at the Site, with levels of petroleum constituents that exceeded the risk based screening levels in groundwater samples collected from temporary monitoring wells on the Site.

January 24, 2017 –

- The Division confirmed a release from the former gasoline UST located at the Green Electric Site. Specific petroleum additives documented in the phase II assessment report samples are consistent with gasoline production around 1988.
- The Division determined that the release was eligible for cleanup using SUPERB funds.
- The Division sent Keenan Oil a letter, that as the tank owner, Keenan Oil must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds.

II. RELEVANT LAW

a) S.C. Code § 44-2-110 (1988).

The 1988 SUPERB Act established a general grace period (amnesty) "beginning on January 1, 1988 and ending on December 31, 1989," for reporting petroleum releases from underground storage tanks (USTs). S.C. Code § 44-2-110 (1988).

> Pursuant thereto, the department shall establish reasonable requirements for the written **reporting of petroleum releases** and distribute the forms ... to be used for **the purpose of reporting petroleum releases**. Until the forms are available for distribution, the department shall take **reports of these releases** however made but shall notify any person making a report that a written **report of the release** will be required by the department at a later time, the form for which will be provided by the department. All ***sites*** **involving releases** from underground storage tanks **reported** to the department any time from midnight on December 31, 1987, to midnight on December 31, 1989, regardless of whether the **release** occurred before or after January 1, 1988, are **qualified *sites*** for the expenditure of funds from the Superb Account, provided that a written report is filed with respect thereto. ...

S.C. Code § 44-2-110 (1988). (emphasis added).

b) S.C. Code §44-2-130(A) (1988).

The 1988 SUPERB Act also established that the amount of site rehabilitation costs from the SUPERB Account was dependent upon when the **release** was reported to the department, as provided under § 44-2-110.

> To encourage voluntary rehabilitation, a person conducting site rehabilitation under Section 44-2-110, which defines the early detection incentive program... is entitled to...be reimbursed from the Superb Account for reasonable costs incurred in connection with the site rehabilitation if prior approval therefor is obtained from the department. **Prior to or during the grace period established under the early detection incentive program**, the person is eligible ... for all reasonable costs incurred in connection with site rehabilitation. **Subsequent to the grace period**...the person is eligible ... for reasonable costs incurred in excess of one hundred thousand dollars ["deductible"]...[1]

S.C. Code §44-2-130(A) (1988). (emphasis added).

c) 1985 UST Control Regulations, R. 61-92.

The 1985 UST Control Regulations, R. 61-92, preceded the 1988 SUPERB Act.[2] These regulations set forth requirements for abandonment of USTs, including an annual reporting

[1] In 1990, the deductible amount was lowered from "one hundred thousand dollars" to "twenty-five thousand dollars." See 1990 Act No. 473, Section 7.

[2] The 1985 UST Control Regulations, R. 61-92, were promulgated pursuant to the South Carolina Pollution Control Act, S.C. Code § 48-1-10 et seq, and S.C. Code § 44-55-10 et seq., entitled "Water, Sewage, Waste Disposal and the Like." State Register, Vol. 9, Issue 5, May 24, 1985.

requirement to notify the Department of any USTs abandoned in the past year. The regulations also required reporting of known UST failures that may have resulted in releases. However, the statutory requirement to report a release during the amnesty period was different from the regulatory annual reporting requirement.

i) "The owner or operator of any tank which has been abandoned … shall notify the Department in accordance with the annual reporting requirements in Section R.61-92.7.H." 61-92.12.C. (1985).

ii) "Beginning January 1987, tank owners or operators must submit a report to the Department… if they have within the past calendar year: (1) Abandoned a tank..." 61-92.12.C. (1985).

The purpose of the SUPERB Act is to protect citizens' health, safety, and welfare by creating a regulatory program to reduce the risk of releases from underground storage tanks and conduct site rehabilitation activities for petroleum releases from regulated USTs. The SUPERB Act and the regulations promulgated pursuant to it (S.C. Regs. 61-92, Part 280 and 61-98) set forth requirements for site rehabilitation for releases from USTs and for accessing funds from the SUPERB account. S.C. Code § 44-2-50. The law confers upon the Division the regulatory authority and responsibility to accomplish the purposes of the Act. The S.C. UST Control Regulations 61-92, Part 280 (2008) and SUPERB R. 61-98, Site Rehabilitation and Fund Access Regulations (1997), provide the framework in which the Division must operate. All decisions made by staff must be aligned with these regulations.

III. STAFF RESPONSE TO GROUNDS IN THE REQUEST FOR REVIEW

a) *Keenan Oil contends that it should not have to pay any deductible for the cleanup of the release at the Green Electric Site, because during the grace period Keenan Oil reported that it removed a UST from the Green Electric Site.*

Keenan Oil submitted a letter to the Department, dated March 14, 1989, with the subject line "Re: Annual Registration Fee for UST" (1989 Tank Fee Notification). Keenan Oil's 1989 Tank Fee Notification did not report any releases. The 1989 Tank Fee Notification was submitted in accordance with the regulatory requirement that tank owners or operators must annually notify the Department of any tanks abandoned[3] within the past calendar year. S.C. Reg. 61-92.7.H. (1985); S.C. Reg. 61-92.12.C. (1985).

In its 1989 Tank Fee Notification, Keenan Oil made the following requests, "[p]er the South Carolina Underground Storage Tank Control regulations R.61-92-7, please receive the below list as notification of tanks no longer in operation" and "[p]lease remove all the above equipment from the annual registration fee charge." The 1989 Tank Fee Notification indicated that Keenan Oil "removed and disposed of" a tank from the Green Electric Site prior to December 24, 1988.

[3] "Abandoned tank" means a tank which has had all regulated substances removed and which is not intended to be returned to operation. R.61-92.3.A. (1985).

Keenan Oil submitted the 1989 Tank Fee Notification during the amnesty period. **This notification did not report a release. Notification of tank removal from a Site is not notification of a release.** Keenan Oil did not report any release at the Green Electric Site during the amnesty period. However, Keenan Oil did report releases at several other sites during the amnesty period. Keenan Oil reported 13 releases prior to July 1, 1993, including reporting a release on June 30, 1993, the last day of the amnesty period. (Attachment 1)

In 2016, subsequent to the grace period, the release at the Green Electric Site was reported to the Department by another party, not Keenan Oil. This release is qualified for SUPERB funds after the deductible has been paid. Therefore, Keenan Oil is responsible for paying the deductible prior to accessing SUPERB funds for this Site.

b) *Keenan Oil contends it is qualified to receive SUPERB funds to cover all reasonable costs incurred in connection with site rehabilitation, regardless of when the release occurred, and is not responsible for any deductible before receiving SUPERB funds, because Keenan Oil reported the site to the Department during the grace period under the law existing at the time of tank removal.*

The 1988 SUPERB Act was the statute in effect at the time Keenan Oil reported the removal of the UST from the Site. Section 44-2-110 of the 1988 SUPERB Act stated, "[a]ll sites involving releases from underground storage tanks reported to the department any time from midnight on December 31, 1987 to midnight on December 31, 1989, regardless of whether the release occurred before or after January 1, 1988, are qualified sites for the expenditure of funds from the SUPERB Account, **provided that a written report is filed with respect thereto**."

Section 44-2-130 of the 1988 SUPERB Act addressed compensation from the SUPERB account and referred to § 44-2-110 to define the early detection incentive program. Section 44-2-110 required that a release be reported to the Department, not simply a site. Under § 44-2-130(A), a person who reported a release "[p]rior to or during the grace period" would be eligible for reimbursement of "all reasonable costs … for site rehabilitation," up to the statutory maximum, without having to meet any deductible. However, a person who reported a release "[s]ubsequent to the grace period" would be eligible for reimbursement of "reasonable costs … in excess of" the deductible, up to the statutory maximum.

The plain language of § 44-2-110 (1988) states multiple times that the subject of what was to be reported was the "release," and not the site. In 1995, the Legislature amended the SUPERB Act to clarify its intent that several sections, including §§ 44-2-110, 44-2-130, applied to **releases** at a site rather than to sites. See 1995 Act no. 145, Part II, Section 2E. Thus both the 1988 SUPERB Act as well as the version current today, as amended in 1995, require a person to make a "written report of a release" and not only of a site, during the grace period in order to be eligible for all reasonable costs.

The 1989 Tank Fee Notification did not include any indication or sample results that would identify there was a release at the Site. Keenan Oil did not report a release at the Green

Electric Site during the amnesty period established in the 1988 SUBPERB Act therefore, Keenan Oil must be responsible for the $25,000 deductible prior to accessing SUPERB.

c) *Keenan Oil contends that this 2017 staff decision is in direct conflict with a 2008 DHEC Board Decision.*

A 2008 decision determined in that case that Keenan Oil would not be required to pay the deductible for a release at the Carolina Tractor and Equipment Site. The 2008 Board Decision did not make any substantive findings or give any indication as to why it made such a decision. Determinations involving the SUPERB Account are fact-specific. This Board's decision regarding this matter should be determined based upon the facts before it today.

The staff decision at issue today is for a release reported on December 2, 2016. Section 44-2-110 states "all releases from USTs reported to the department any time from midnight on December 31, 1987 to midnight on June 30, 1993… are qualified for expenditure of funds from the SUPERB account, provided that a written report is filed with respect to it." The release at issue today was not reported prior to midnight on June 30, 1993.

d) *Keenan Oil contends that it removed the UST at the Green Electric Site and made the required reporting to the Department in accordance with the regulations in effect at the time of the removal.*

The requirement to report a release during the amnesty period was in the 1988 statute, and not required in the UST regulations in effect when Keenan Oil removed the tank from the Green Electric Site. The 1985 UST regulations required tank abandonment notification found in R.61-92.7.H. Keenan Oil notified the Department of tanks removed per the applicable regulatory requirements, and was therefore no longer subject to the responsibility for tank fees, providing financial responsibility and maintaining those USTs. However, Keenan's 1989 Tank Fee Notification did not report a release at this Site.

IV. REQUESTED ACTION

The Department respectfully requests that the Board deny the Request for Final Review, thereby upholding the staff determination that the release at the Green Electric Site, reported on December 2, 2016, qualifies for SUPERB funding, following Keenan Oil's satisfaction of the twenty-five thousand dollar deductible required under the SUPERB Act.

Attachments:

Attachment 1 – Keenan Release Report made June 30, 1993
Attachment 2 – Release declaration letter
Attachment 3 – Phase II assessment report and memo, received December 2, 2016

Attachment 1

South Carolina DHEC
Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201

S.C. UNDERGROUND STORAGE TANKS
REPORT OF SUSPECTED/CONFIRMED RELEASE

TODAY'S DATE: 6/29/93

REPORTED BY: VIRGINIA, INC. - ETE DIVISION (print) **PHONE:** 957-6270

ADDRESS: 1445 MISEAH CHURCH ROAD

LEXINGTON, SC 29072

OWNER NAME: KEENAN OIL CO. **PHONE:** 256-0667

FACILITY NAME: Eau Claire 66

ADDRESS: Monticello Road

Columbia, SC

S.C. UST REGISTRATION #: 07197

DATE DISCOVERED: 6/23/93

HOW DISCOVERED: LABORATORY ANALYSIS

TYPE OF PRODUCT RELEASED: GASOLINE

RECEIVED
JUN 30 1993
Groundwater Protection Division

HOW RELEASE OCCURRED:

Release from UST system.

INITIAL CLEAN-UP MEASURES TAKEN:

UST system permanently closed.

SIGNATURE OF PERSON COMPLETING FORM:

Be sure to notify all other relevant parties
(i.e., Facility Owner, Adjacent Property Owners, EPA, Fire Department, Etc.)
and to follow the directives of Subpart E of the S.C. Underground Storage Tank Control Regulations.

Attachment 32

dhec
Healthy People Healthy Communities

January 24, 2017

Keenan Oil Co., Inc.
PO Box 3218
Columbia, SC 29230-3218

Re: **Underground Storage Tank (UST)** Permit – 07705
Green Electric Co., 2248 Sumter St., Columbia, SC
Report received – December 2, 2016

Dear Sir or Madam:

An assessment report received by the UST Management Division on December 2, 2016, indicates that groundwater collected from a temporary monitoring well at this location is contaminated with petroleum constituents. A file review indicates Keenan Oil Co., Inc. as the tank owner at the time of tank removal and therefore, the responsible party for the petroleum contamination documented in the Phase II assessment. The State Underground Petroleum Environmental Response Bank (SUPERB) Account provides financial assistance for the cleanup of a site contaminated by a release from a regulated UST system provided that the facility associated with the release meets certain eligibility criteria. The Division has determined that this release is eligible for cleanup using SUPERB funds. The responsible party must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds.

The SUPERB Act Section 44-2-130(E)(1) states: "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the Superb Account for site rehabilitation shall submit a written application to the department." For your convenience, a SUPERB Account Application/Statement of Insurance form is enclosed. Please complete and return the attached form. You must request access to the SUPERB Account in order for the Division to complete the SUPERB qualification process.

South Carolina UST Control Regulation 61-92, Section 280.93(a) and 280.113 of the South Carolina Underground Storage Tank Control Regulations requires that tank owners submit and maintain proof of financial responsibility (FR) until subsequent corrective action is complete.

Should you have any questions pertaining to this matter, please contact me at (803) 898-0647.

Respectfully,

Denise M. Place

Denise M. Place
Regulatory Compliance Section
UST Management Division
Bureau of Land and Waste Management

Enclosure

dhec

Superb Account Application
Ust Management Division

Pursuant to the State Underground Petroleum Environmental Response Bank (SUPERB) Act 44-2-130(E)(1): "An owner or operator of an underground storage tank or his agent seeking to qualify for compensation from the SUPERB Account for site rehabilitation shall submit a written application to the department."

Permit #: _____ Facility Name: _____

Facility Address: _____

Owner Name: _____

Owner Address: _____

Owner Phone #: _____

For the following section, circle **YES** or **NO:**

YES or NO I request compensation from the SUPERB Account for the release discovered/reported on _____.

You/your company must satisfy a $25,000.00 deductible prior to the Division using SUPERB funds (Pursuant to the SUBERB Act 44-2-130). According to department records, you/your company had _____ as your financial responsibility mechanism at the time the release was reported. If this information is inaccurate, please correct it by checking the appropriate mechanism below:

☐ **Letter of Credit** ☐ **Insurance Policy** ☐ **Self-Insurance** ☐ **Surety Bond** ☐ **Guarantee**

INSURANCE STATEMENT

This site is potentially eligible to receive state monies to assist in site rehabilitation. Before eligibility for the SUPERB funds can be determined, written confirmation of the existence or non-existence of an environmental insurance policy for this site is required. Please circle **YES** or **NO** with regard to the following:

Is there now, or has there ever been an insurance policy or other financial mechanism that covers this UST release?
YES or NO

My policy provider is _____

The policy number is _____

The policy deductible is _____ Policy limit: _____

If you have this type of insurance, please include a copy of the policy with this report.

Owner Signature: _____

Print Signatory Name: _____

Date: _____

Sworn before me this _____ day

of _____, 20_____.

_____
Notary Public (Signature)

for the State of _____
(if other than South Carolina, affix seal)

SCHDEC, UST Management Division, 2600 Bull Street, Columbia, SC 29201, PHONE (803) 898-0589, FAX (803) 898-0673, www.scdhec.gov/ust

Attachment 3

dhec
Healthy People Healthy Communities.

MEMORANDUM

To: Chris Doll, P.G., Section Manager
Assessment Section
UST Management Division, BLWM

From: Denise M. Place DMP
Regulatory Compliance Section
UST Management Division, BLWM

Through: Eric Cathcart, Section Manager
Regulatory Compliance Section
UST Management Division, BLWM

Date: January 23, 2017

Re: UST Permit – 07705
Green Electric Co., 2248 Sumter St., Columbia, SC
Release reported – December 2, 2016

Our records indicate that one gasoline UST was owned by Keenan Oil Co., Inc. at the referenced location. The UST is listed as removed from the ground but the Division has no record of having received a closure report and does not have a removal date. No additional information exists and the file has been purged.

The Division received a Phase II assessment report on December 2, 2016 indicating that petroleum constituents exceed RBSL's for groundwater collected from a temporary monitoring well on site.

No previous releases have been reported for this location and there are no known offsite sources. Therefore, a release has been entered with Keenan Oil Co., Inc. as the responsible party.

Due to the lack of compliance history for this facility, a Substantial Compliance Worksheet will not be completed. The Division will favor eligibility and find this release in substantial compliance.

Site Name/ID# Greene Electric 07705
Release # _____ For UST# _____ Release Report Date 12-2-16
County Richland

Free Product Reported? Yes/No Impacted water supply well reported? Yes/No
Receptor w/in 1000 feet of UST system? (Well, Surface water body, wetland, other)

Triage (Indicate type of submittal)
CR ___
AR ___

Worst Case Sample	RBSL (mg/kg)	(ug/kg)	Soil #	RBSL (ug/l)	Water (ug/l)/#
Benzene	.007	7		5	180
Toluene	1.45	1450		1000	UD
Ethylbenzene	1.15	1150		700	
Xylenes	14.5	1450		10,000	
Naphthalene (8260)	.036	36		25	
Naphthalene (8270)	.036	36		25	
PAH's					
Benzo(a)anthracene	.66	660			
Benzo(b)flouranthene	.66	660			
Benzo(k)flouranthene	.66	660			
Chrysene	.66	660			
Dibenz(a,h)anthracene	.66	660			
Other					
MTBE (water only)				40	11
1,2-DCA				5	8.5
EDB				.05	
Other _____					

POTENTIAL SC DENIAL? YES / NO

1. All USTs Registered? (Yes) / No / NA
2. All Applicable Annual Fees Paid? Yes / No / (NA)
3. Financial Responsibility Mechanism verified? Yes /No/ NA Type None
4. Insurance Statement Requested? Yes / No/NA Received? Yes/No
5. UST Status (account for all USTs in database)
   1 USTs Permanently Closed Date Closed _____ Last Used Date _____
   __ USTs CIU & Passed TT Date Tested _____ Date Repaired _____
6. RP – Owner signature? Yes / No
7. Site Map Requested? Yes/No Received? (Yes) / No
8. AST's present? Yes/No _____

NFA? Yes___ No___
Manager Approval_____

Not Ranked

07705

Fw: 2244 Sumter Street

McInnis, Jonathan

Fri 12/2/2016 11:29 AM

To: Place, Denise <placedm@dhec.sc.gov>;

1 attachments (1 MB)

Site Plan and Lab Data.pdf;

Your #7705 I believe. Can someone give Andy feedback on these results? I can tell you the 1,2-DCA detection would only make the site our lowest priority here and likely we would not open any investigation. Thanks!

Jonathan

Jonathan G. McInnis, Program Manager
Federal & State Site Assessment Section
Division of Site Assessment, Remediation, and Revitalization
Bureau of Land & Waste Management
S.C. Dept. of Health & Environmental Control
2600 Bull Street
Columbia, SC 29201
Office: (803) 898-0802
Fax: (803) 898-1297
mcinnijg@dhec.sc.gov
Connect: www.scdhec.gov Facebook Twitter

From: Andy Wilson <awilson@armenv.com>
Sent: Friday, December 2, 2016 10:04 AM
To: McInnis, Jonathan
Cc: Michele McLeod
Subject: 2244 Sumter Street

Good morning. Attached is information on a recent Phase II that we have completed. The site is the former location of Green Electric Company. According to regulatory data we evaluated during a Phase I, this site had a 1,000 gallon UST that was removed in 1991. The property is currently owned by First Citizens Bank (Raleigh, NC) through foreclosure.

We represent the potential buyer and we have recommended that we get y'all's decision regarding any additional work that may be required. I will get you the 1903 forms early next week. Meanwhile, please evaluate this data and let us know your opinion. Thanks.

Andrew M. Wilson, P.G.
ARM Environmental Services, Inc.

1210 First Street South
Columbia, SC 29209
awilson@armenv.com
ph: 803 783-3314
cell: 803 269-3908

Attachment 2

SHEALY ENVIRONMENTAL SERVICES, INC.

Report of Analysis

ARM Environmental Services, Inc.
1210 1st Street S. Ext.
Columbia, SC 29209
Attention: Michael Faris

Project Name: **2244 Sumter St**

Project Number: **08-281-16**

Lot Number: **RK21011**

Date Completed: **11/28/2016**

Lucas Odom
Project Manager

LABORATORY ACCREDITATION BUREAU ACCREDITED

The following non-paginated documents are considered part of this report: Chain of Custody Record and Sample Receipt Checklist.

Case Narrative
ARM Environmental Services, Inc.
Lot Number: RK21011

This Report of Analysis contains the analytical result(s) for the sample(s) listed on the Sample Summary following this Case Narrative. The sample receiving date is documented in the header information associated with each sample.

All results listed in this report relate only to the samples that are contained within this report.

Sample receipt, sample analysis, and data review have been performed in accordance with the most current approved NELAC standards, the Shealy Environmental Services, Inc. ("Shealy") Quality Assurance Management Plan (QAMP), standard operating procedures (SOPs), and Shealy policies. Any exceptions to the NELAC standards, the QAMP, SOPs or policies are qualified on the results page or discussed below.

If you have any questions regarding this report please contact the Shealy Project Manager listed on the cover page.

Sample Summary

ARM Environmental Services, Inc.

Lot Number: RK21011

Sample Number	Sample ID	Matrix	Date Sampled	Date Received
001	TMW-1	Aqueous	11/18/2016 1530	11/21/2016
002	TMW-2	Aqueous	11/18/2016 1600	11/21/2016
003	TMW-3	Aqueous	11/18/2016 1700	11/21/2016

(3 samples)

Executive Summary
ARM Environmental Services, Inc.
Lot Number: RK21011

Sample	Sample ID	Matrix	Parameter	Method	Result	Q	Units	Page
001	TMW-1	Aqueous	Benzene	8260B	180		ug/L	5
001	TMW-1	Aqueous	1,2-Dichloroethane	8260B	8.5		ug/L	5
001	TMW-1	Aqueous	Methyl tertiary butyl ether	8260B	11		ug/L	5
002	TMW-2	Aqueous	Benzene	8260B	10		ug/L	7
002	TMW-2	Aqueous	Chloroform	8260B	6.0		ug/L	7

(5 detections)

Client: ARM Environmental Services, Inc.
Description: TMW-1
Date Sampled: 11/18/2016 1530
Date Received: 11/21/2016

Laboratory ID: RK21011-001
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1157	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
Acetone	67-64-1	8260B	ND		20	ug/L	1
Benzene	**71-43-2**	**8260B**	**180**		**5.0**	**ug/L**	**1**
Bromodichloromethane	75-27-4	8260B	ND		5.0	ug/L	1
Bromoform	75-25-2	8260B	ND		5.0	ug/L	1
Bromomethane (Methyl bromide)	74-83-9	8260B	ND		5.0	ug/L	1
2-Butanone (MEK)	78-93-3	8260B	ND		10	ug/L	1
Carbon disulfide	75-15-0	8260B	ND		5.0	ug/L	1
Carbon tetrachloride	56-23-5	8260B	ND		5.0	ug/L	1
Chlorobenzene	108-90-7	8260B	ND		5.0	ug/L	1
Chloroethane	75-00-3	8260B	ND		5.0	ug/L	1
Chloroform	67-66-3	8260B	ND		5.0	ug/L	1
Chloromethane (Methyl chloride)	74-87-3	8260B	ND		5.0	ug/L	1
Cyclohexane	110-82-7	8260B	ND		5.0	ug/L	1
1,2-Dibromo-3-chloropropane (DBCP)	96-12-8	8260B	ND		5.0	ug/L	1
Dibromochloromethane	124-48-1	8260B	ND		5.0	ug/L	1
1,2-Dibromoethane (EDB)	106-93-4	8260B	ND		5.0	ug/L	1
1,2-Dichlorobenzene	95-50-1	8260B	ND		5.0	ug/L	1
1,3-Dichlorobenzene	541-73-1	8260B	ND		5.0	ug/L	1
1,4-Dichlorobenzene	106-46-7	8260B	ND		5.0	ug/L	1
Dichlorodifluoromethane	75-71-8	8260B	ND		5.0	ug/L	1
1,1-Dichloroethane	75-34-3	8260B	ND		5.0	ug/L	1
1,2-Dichloroethane	**107-06-2**	**8260B**	**8.5**		**5.0**	**ug/L**	**1**
1,1-Dichloroethene	75-35-4	8260B	ND		5.0	ug/L	1
cis-1,2-Dichloroethene	156-59-2	8260B	ND		5.0	ug/L	1
trans-1,2-Dichloroethene	156-60-5	8260B	ND		5.0	ug/L	1
1,2-Dichloropropane	78-87-5	8260B	ND		5.0	ug/L	1
cis-1,3-Dichloropropene	10061-01-5	8260B	ND		5.0	ug/L	1
trans-1,3-Dichloropropene	10061-02-6	8260B	ND		5.0	ug/L	1
Ethylbenzene	100-41-4	8260B	ND		5.0	ug/L	1
2-Hexanone	591-78-6	8260B	ND		10	ug/L	1
Isopropylbenzene	98-82-8	8260B	ND		5.0	ug/L	1
Methyl acetate	79-20-9	8260B	ND		5.0	ug/L	1
Methyl tertiary butyl ether (MTBE)	**1634-04-4**	**8260B**	**11**		**5.0**	**ug/L**	**1**
4-Methyl-2-pentanone	108-10-1	8260B	ND		10	ug/L	1
Methylcyclohexane	108-87-2	8260B	ND		5.0	ug/L	1
Methylene chloride	75-09-2	8260B	ND		5.0	ug/L	1
Styrene	100-42-5	8260B	ND		5.0	ug/L	1
1,1,2,2-Tetrachloroethane	79-34-5	8260B	ND		5.0	ug/L	1
Tetrachloroethene	127-18-4	8260B	ND		5.0	ug/L	1
Toluene	108-88-3	8260B	ND		5.0	ug/L	1

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and > MDL
E = Quantitation of compound exceeded the calibration range
P = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Client: ARM Environmental Services, Inc.
Description: TMW-1
Date Sampled: 11/18/2016 1530
Date Received: 11/21/2016

Laboratory ID: RK21011-001
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1157	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
1,1,2-Trichloro-1,2,2-Trifluoroethane	76-13-1	8260B	ND		5.0	ug/L	1
1,2,4-Trichlorobenzene	120-82-1	8260B	ND		5.0	ug/L	1
1,1,1-Trichloroethane	71-55-6	8260B	ND		5.0	ug/L	1
1,1,2-Trichloroethane	79-00-5	8260B	ND		5.0	ug/L	1
Trichloroethene	79-01-6	8260B	ND		5.0	ug/L	1
Trichlorofluoromethane	75-69-4	8260B	ND		5.0	ug/L	1
Vinyl chloride	75-01-4	8260B	ND		2.0	ug/L	1
Xylenes (total)	1330-20-7	8260B	ND		5.0	ug/L	1

Surrogate	Q	Run 1 % Recovery	Acceptance Limits
1,2-Dichloroethane-d4		89	70-130
Bromofluorobenzene		98	70-130
Toluene-d8		102	70-130

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and ≥ MDL
E = Quantitation of compound exceeded the calibration range
F = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Client: ARM Environmental Services, Inc.
Description: TMW-2
Date Sampled: 11/18/2016 1600
Date Received: 11/21/2016

Laboratory ID: RK21011-002
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1221	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
Acetone	67-64-1	8260B	ND		20	ug/L	1
Benzene	**71-43-2**	**8260B**	**10**		**5.0**	**ug/L**	**1**
Bromodichloromethane	75-27-4	8260B	ND		5.0	ug/L	1
Bromoform	75-25-2	8260B	ND		5.0	ug/L	1
Bromomethane (Methyl bromide)	74-83-9	8260B	ND		5.0	ug/L	1
2-Butanone (MEK)	78-93-3	8260B	ND		10	ug/L	1
Carbon disulfide	75-15-0	8260B	ND		5.0	ug/L	1
Carbon tetrachloride	56-23-5	8260B	ND		5.0	ug/L	1
Chlorobenzene	108-90-7	8260B	ND		5.0	ug/L	1
Chloroethane	75-00-3	8260B	ND		5.0	ug/L	1
Chloroform	**67-66-3**	**8260B**	**6.0**		**5.0**	**ug/L**	**1**
Chloromethane (Methyl chloride)	74-87-3	8260B	ND		5.0	ug/L	1
Cyclohexane	110-82-7	8260B	ND		5.0	ug/L	1
1,2-Dibromo-3-chloropropane (DBCP)	96-12-8	8260B	ND		5.0	ug/L	1
Dibromochloromethane	124-48-1	8260B	ND		5.0	ug/L	1
1,2-Dibromoethane (EDB)	106-93-4	8260B	ND		5.0	ug/L	1
1,2-Dichlorobenzene	95-50-1	8260B	ND		5.0	ug/L	1
1,3-Dichlorobenzene	541-73-1	8260B	ND		5.0	ug/L	1
1,4-Dichlorobenzene	106-46-7	8260B	ND		5.0	ug/L	1
Dichlorodifluoromethane	75-71-8	8260B	ND		5.0	ug/L	1
1,1-Dichloroethane	75-34-3	8260B	ND		5.0	ug/L	1
1,2-Dichloroethane	107-06-2	8260B	ND		5.0	ug/L	1
1,1-Dichloroethene	75-35-4	8260B	ND		5.0	ug/L	1
cis-1,2-Dichloroethene	156-59-2	8260B	ND		5.0	ug/L	1
trans-1,2-Dichloroethene	156-60-5	8260B	ND		5.0	ug/L	1
1,2-Dichloropropane	78-87-5	8260B	ND		5.0	ug/L	1
cis-1,3-Dichloropropene	10061-01-5	8260B	ND		5.0	ug/L	1
trans-1,3-Dichloropropene	10061-02-6	8260B	ND		5.0	ug/L	1
Ethylbenzene	100-41-4	8260B	ND		5.0	ug/L	1
2-Hexanone	591-78-6	8260B	ND		10	ug/L	1
Isopropylbenzene	98-82-8	8260B	ND		5.0	ug/L	1
Methyl acetate	79-20-9	8260B	ND		5.0	ug/L	1
Methyl tertiary butyl ether (MTBE)	1634-04-4	8260B	ND		5.0	ug/L	1
4-Methyl-2-pentanone	108-10-1	8260B	ND		10	ug/L	1
Methylcyclohexane	108-87-2	8260B	ND		5.0	ug/L	1
Methylene chloride	75-09-2	8260B	ND		5.0	ug/L	1
Styrene	100-42-5	8260B	ND		5.0	ug/L	1
1,1,2,2-Tetrachloroethane	79-34-5	8260B	ND		5.0	ug/L	1
Tetrachloroethene	127-18-4	8260B	ND		5.0	ug/L	1
Toluene	108-88-3	8260B	ND		5.0	ug/L	1

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and ≥ MDL
E = Quantitation of compound exceeded the calibration range
P = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Client: ARM Environmental Services, Inc.
Description: TMW-2
Date Sampled: 11/18/2016 1600
Date Received: 11/21/2016

Laboratory ID: RK21011-002
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1221	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
1,1,2-Trichloro-1,2,2-Trifluoroethane	76-13-1	8260B	ND		5.0	ug/L	1
1,2,4-Trichlorobenzene	120-82-1	8260B	ND		5.0	ug/L	1
1,1,1-Trichloroethane	71-55-6	8260B	ND		5.0	ug/L	1
1,1,2-Trichloroethane	79-00-5	8260B	ND		5.0	ug/L	1
Trichloroethene	79-01-6	8260B	ND		5.0	ug/L	1
Trichlorofluoromethane	75-69-4	8260B	ND		5.0	ug/L	1
Vinyl chloride	75-01-4	8260B	ND		2.0	ug/L	1
Xylenes (total)	1330-20-7	8260B	ND		5.0	ug/L	1

Surrogate	Q	Run 1 % Recovery	Acceptance Limits
1,2-Dichloroethane-d4		92	70-130
Bromofluorobenzene		102	70-130
Toluene-d8		104	70-130

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and ≥ MDL
E = Quantitation of compound exceeded the calibration range
P = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Client: ARM Environmental Services, Inc.
Description: TMW-3
Date Sampled: 11/18/2016 1700
Date Received: 11/21/2016

Laboratory ID: RK21011-003
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1244	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
Acetone	67-64-1	8260B	ND		20	ug/L	1
Benzene	71-43-2	8260B	ND		5.0	ug/L	1
Bromodichloromethane	75-27-4	8260B	ND		5.0	ug/L	1
Bromoform	75-25-2	8260B	ND		5.0	ug/L	1
Bromomethane (Methyl bromide)	74-83-9	8260B	ND		5.0	ug/L	1
2-Butanone (MEK)	78-93-3	8260B	ND		10	ug/L	1
Carbon disulfide	75-15-0	8260B	ND		5.0	ug/L	1
Carbon tetrachloride	56-23-5	8260B	ND		5.0	ug/L	1
Chlorobenzene	108-90-7	8260B	ND		5.0	ug/L	1
Chloroethane	75-00-3	8260B	ND		5.0	ug/L	1
Chloroform	67-66-3	8260B	ND		5.0	ug/L	1
Chloromethane (Methyl chloride)	74-87-3	8260B	ND		5.0	ug/L	1
Cyclohexane	110-82-7	8260B	ND		5.0	ug/L	1
1,2-Dibromo-3-chloropropane (DBCP)	96-12-8	8260B	ND		5.0	ug/L	1
Dibromochloromethane	124-48-1	8260B	ND		5.0	ug/L	1
1,2-Dibromoethane (EDB)	106-93-4	8260B	ND		5.0	ug/L	1
1,2-Dichlorobenzene	95-50-1	8260B	ND		5.0	ug/L	1
1,3-Dichlorobenzene	541-73-1	8260B	ND		5.0	ug/L	1
1,4-Dichlorobenzene	106-46-7	8260B	ND		5.0	ug/L	1
Dichlorodifluoromethane	75-71-8	8260B	ND		5.0	ug/L	1
1,1-Dichloroethane	75-34-3	8260B	ND		5.0	ug/L	1
1,2-Dichloroethane	107-06-2	8260B	ND		5.0	ug/L	1
1,1-Dichloroethene	75-35-4	8260B	ND		5.0	ug/L	1
cis-1,2-Dichloroethene	156-59-2	8260B	ND		5.0	ug/L	1
trans-1,2-Dichloroethene	156-60-5	8260B	ND		5.0	ug/L	1
1,2-Dichloropropane	78-87-5	8260B	ND		5.0	ug/L	1
cis-1,3-Dichloropropene	10061-01-5	8260B	ND		5.0	ug/L	1
trans-1,3-Dichloropropene	10061-02-6	8260B	ND		5.0	ug/L	1
Ethylbenzene	100-41-4	8260B	ND		5.0	ug/L	1
2-Hexanone	591-78-6	8260B	ND		10	ug/L	1
Isopropylbenzene	98-82-8	8260B	ND		5.0	ug/L	1
Methyl acetate	79-20-9	8260B	ND		5.0	ug/L	1
Methyl tertiary butyl ether (MTBE)	1634-04-4	8260B	ND		5.0	ug/L	1
4-Methyl-2-pentanone	108-10-1	8260B	ND		10	ug/L	1
Methylcyclohexane	108-87-2	8260B	ND		5.0	ug/L	1
Methylene chloride	75-09-2	8260B	ND		5.0	ug/L	1
Styrene	100-42-5	8260B	ND		5.0	ug/L	1
1,1,2,2-Tetrachloroethane	79-34-5	8260B	ND		5.0	ug/L	1
Tetrachloroethene	127-18-4	8260B	ND		5.0	ug/L	1
Toluene	108-88-3	8260B	ND		5.0	ug/L	1

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and ≥ MDL
E = Quantitation of compound exceeded the calibration range
P = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless tagged with a "W"

Client: ARM Environmental Services, Inc.
Description: TMW-3
Date Sampled: 11/18/2016 1700
Date Received: 11/21/2016

Laboratory ID: RK21011-003
Matrix: Aqueous

Volatile Organic Compounds by GC/MS

Run	Prep Method	Analytical Method	Dilution	Analysis Date	Analyst	Prep Date	Batch
1	5030B	8260B	1	11/26/2016 1244	TML		27802

Parameter	CAS Number	Analytical Method	Result	Q	PQL	Units	Run
1,1,2-Trichloro-1,2,2-Trifluoroethane	76-13-1	8260B	ND		5.0	ug/L	1
1,2,4-Trichlorobenzene	120-82-1	8260B	ND		5.0	ug/L	1
1,1,1-Trichloroethane	71-55-6	8260B	ND		5.0	ug/L	1
1,1,2-Trichloroethane	79-00-5	8260B	ND		5.0	ug/L	1
Trichloroethene	79-01-6	8260B	ND		5.0	ug/L	1
Trichlorofluoromethane	75-69-4	8260B	ND		5.0	ug/L	1
Vinyl chloride	75-01-4	8260B	ND		2.0	ug/L	1
Xylenes (total)	1330-20-7	8260B	ND		5.0	ug/L	1

Surrogate	Q	Run 1 % Recovery	Acceptance Limits
1,2-Dichloroethane-d4		92	70-130
Bromofluorobenzene		94	70-130
Toluene-d8		99	70-130

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
B = Detected in the method blank
J = Estimated result < PQL and ≥ MDL
E = Quantitation of compound exceeded the calibration range
P = The RPD between two GC columns exceeds 40%
H = Out of holding time
N = Recovery is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

QC Summary

Volatile Organic Compounds by GC/MS - MB

Sample ID: RQ27802-001
Batch: 27802
Analytical Method: 8260B

Matrix: Aqueous
Prep Method: 5030B

Parameter	Result	Q	Dil	PQL	Units	Analysis Date
Acetone	ND		1	20	ug/L	11/26/2016 1057
Benzene	ND		1	5.0	ug/L	11/26/2016 1057
Bromodichloromethane	ND		1	5.0	ug/L	11/26/2016 1057
Bromoform	ND		1	5.0	ug/L	11/26/2016 1057
Bromomethane (Methyl bromide)	ND		1	5.0	ug/L	11/26/2016 1057
2-Butanone (MEK)	ND		1	10	ug/L	11/26/2016 1057
Carbon disulfide	ND		1	5.0	ug/L	11/26/2016 1057
Carbon tetrachloride	ND		1	5.0	ug/L	11/26/2016 1057
Chlorobenzene	ND		1	5.0	ug/L	11/26/2016 1057
Chloroethane	ND		1	5.0	ug/L	11/26/2016 1057
Chloroform	ND		1	5.0	ug/L	11/26/2016 1057
Chloromethane (Methyl chloride)	ND		1	5.0	ug/L	11/26/2016 1057
Cyclohexane	ND		1	5.0	ug/L	11/26/2016 1057
1,2-Dibromo-3-chloropropane (DBCP)	ND		1	5.0	ug/L	11/26/2016 1057
Dibromochloromethane	ND		1	5.0	ug/L	11/26/2016 1057
1,2-Dibromoethane (EDB)	ND		1	5.0	ug/L	11/26/2016 1057
1,4-Dichlorobenzene	ND		1	5.0	ug/L	11/26/2016 1057
1,3-Dichlorobenzene	ND		1	5.0	ug/L	11/26/2016 1057
1,2-Dichlorobenzene	ND		1	5.0	ug/L	11/26/2016 1057
Dichlorodifluoromethane	ND		1	5.0	ug/L	11/26/2016 1057
1,2-Dichloroethane	ND		1	5.0	ug/L	11/26/2016 1057
1,1-Dichloroethane	ND		1	5.0	ug/L	11/26/2016 1057
cis-1,2-Dichloroethene	ND		1	5.0	ug/L	11/26/2016 1057
trans-1,2-Dichloroethene	ND		1	5.0	ug/L	11/26/2016 1057
1,1-Dichloroethene	ND		1	5.0	ug/L	11/26/2016 1057
1,2-Dichloropropane	ND		1	5.0	ug/L	11/26/2016 1057
trans-1,3-Dichloropropene	ND		1	5.0	ug/L	11/26/2016 1057
cis-1,3-Dichloropropene	ND		1	5.0	ug/L	11/26/2016 1057
Ethylbenzene	ND		1	5.0	ug/L	11/26/2016 1057
2-Hexanone	ND		1	10	ug/L	11/26/2016 1057
Isopropylbenzene	ND		1	5.0	ug/L	11/26/2016 1057
Methyl acetate	ND		1	5.0	ug/L	11/26/2016 1057
Methyl tertiary butyl ether (MTBE)	ND		1	5.0	ug/L	11/26/2016 1057
4-Methyl-2-pentanone	ND		1	10	ug/L	11/26/2016 1057
Methylcyclohexane	ND		1	5.0	ug/L	11/26/2016 1057
Methylene chloride	ND		1	5.0	ug/L	11/26/2016 1057
Styrene	ND		1	5.0	ug/L	11/26/2016 1057
1,1,2,2-Tetrachloroethane	ND		1	5.0	ug/L	11/26/2016 1057
Tetrachloroethene	ND		1	5.0	ug/L	11/26/2016 1057
Toluene	ND		1	5.0	ug/L	11/26/2016 1057
1,1,2-Trichloro-1,2,2-Trifluoroethane	ND		1	5.0	ug/L	11/26/2016 1057
1,2,4-Trichlorobenzene	ND		1	5.0	ug/L	11/26/2016 1057
1,1,2-Trichloroethane	ND		1	5.0	ug/L	11/26/2016 1057
1,1,1-Trichloroethane	ND		1	5.0	ug/L	11/26/2016 1057

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
P = The RPD between two GC columns exceeds 40%
J = Estimated result < PQL and ≥ MDL
N = Recovery is out of criteria
* = RPD is out of criteria

Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Note: Calculations are performed before rounding to avoid round-off errors in calculated results

Volatile Organic Compounds by GC/MS - MB

Sample ID: RQ27802-001
Batch: 27802
Analytical Method: 8260B

Matrix: Aqueous
Prep Method: 5030B

Parameter	Result	Q	Dil	PQL	Units	Analysis Date
Trichloroethene	ND		1	5.0	ug/L	11/26/2016 1057
Trichlorofluoromethane	ND		1	5.0	ug/L	11/26/2016 1057
Vinyl chloride	ND		1	2.0	ug/L	11/26/2016 1057
Xylenes (total)	ND		1	5.0	ug/L	11/26/2016 1057

Surrogate	Q	% Rec	Acceptance Limit
Bromofluorobenzene		97	70-130
1,2-Dichloroethane-d4		90	70-130
Toluene-d8		102	70-130

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
P = The RPD between two GC columns exceeds 40%
J = Estimated result < PQL and ≥ MDL
N = Recovery is out of criteria
+ = RPD is out of criteria

Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Note: Calculations are performed before rounding to avoid round-off errors in calculated results

Volatile Organic Compounds by GC/MS - LCS

Sample ID: RQ27802-002 **Matrix:** Aqueous
Batch: 27802 **Prep Method:** 5030B
Analytical Method: 8260B

Parameter	Spike Amount (ug/L)	Result (ug/L)	Q	Dil	% Rec	% Rec Limit	Analysis Date
Acetone	100	92		1	92	60-140	11/26/2016 0959
Benzene	50	45		1	90	70-130	11/26/2016 0959
Bromodichloromethane	50	52		1	104	70-130	11/26/2016 0959
Bromoform	50	48		1	96	70-130	11/26/2016 0959
Bromomethane (Methyl bromide)	50	48		1	95	60-140	11/26/2016 0959
2-Butanone (MEK)	100	95		1	95	60-140	11/26/2016 0959
Carbon disulfide	50	38		1	77	60-140	11/26/2016 0959
Carbon tetrachloride	50	48		1	96	70-130	11/26/2016 0959
Chlorobenzene	50	48		1	97	70-130	11/26/2016 0959
Chloroethane	50	42		1	84	60-140	11/26/2016 0959
Chloroform	50	47		1	95	70-130	11/26/2016 0959
Chloromethane (Methyl chloride)	50	56		1	111	60-140	11/26/2016 0959
Cyclohexane	50	40		1	80	70-130	11/26/2016 0959
1,2-Dibromo-3-chloropropane (DBCP)	50	50		1	101	70-130	11/26/2016 0959
Dibromochloromethane	50	48		1	96	70-130	11/26/2016 0959
1,2-Dibromoethane (EDB)	50	48		1	95	70-130	11/26/2016 0959
1,4-Dichlorobenzene	50	47		1	94	70-130	11/26/2016 0959
1,3-Dichlorobenzene	50	49		1	98	70-130	11/26/2016 0959
1,2-Dichlorobenzene	50	49		1	97	70-130	11/26/2016 0959
Dichlorodifluoromethane	50	51		1	101	60-140	11/26/2016 0959
1,2-Dichloroethane	50	48		1	97	70-130	11/26/2016 0959
1,1-Dichloroethane	50	45		1	91	70-130	11/26/2016 0959
cis-1,2-Dichloroethene	50	43		1	87	70-130	11/26/2016 0959
trans-1,2-Dichloroethene	50	43		1	86	70-130	11/26/2016 0959
1,1-Dichloroethene	50	42		1	83	70-130	11/26/2016 0959
1,2-Dichloropropane	50	48		1	96	70-130	11/26/2016 0959
trans-1,3-Dichloropropene	50	47		1	95	70-130	11/26/2016 0959
cis-1,3-Dichloropropene	50	48		1	95	70-130	11/26/2016 0959
Ethylbenzene	50	50		1	100	70-130	11/26/2016 0959
2-Hexanone	100	110		1	106	60-140	11/26/2016 0959
Isopropylbenzene	50	48		1	96	70-130	11/26/2016 0959
Methyl acetate	50	41		1	82	60-140	11/26/2016 0959
Methyl tertiary butyl ether (MTBE)	50	43		1	86	70-130	11/26/2016 0959
4-Methyl-2-pentanone	100	110		1	105	60-140	11/26/2016 0959
Methylcyclohexane	50	44		1	89	70-130	11/26/2016 0959
Methylene chloride	50	41		1	81	70-130	11/26/2016 0959
Styrene	50	52		1	104	70-130	11/26/2016 0959
1,1,2,2-Tetrachloroethane	50	50		1	99	70-130	11/26/2016 0959
Tetrachloroethene	50	48		1	95	70-130	11/26/2016 0959
Toluene	50	49		1	98	70-130	11/26/2016 0959
1,1,2-Trichloro-1,2,2-Trifluoroethane	50	41		1	82	70-130	11/26/2016 0959
1,2,4-Trichlorobenzene	50	46		1	92	70-130	11/26/2016 0959
1,1,2-Trichloroethane	50	48		1	96	70-130	11/26/2016 0959
1,1,1-Trichloroethane	50	46		1	93	70-130	11/26/2016 0959

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
P = The RPD between two GC columns exceeds 40%
J = Estimated result < PQL and ≥ MDL
N = Recovery is out of criteria
+ = RPD is out of criteria
Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "W"

Note: Calculations are performed before rounding to avoid round-off errors in calculated results

Volatile Organic Compounds by GC/MS - LCS

Sample ID: RQ27602-002
Batch: 27602
Analytical Method: 8260B

Matrix: Aqueous
Prep Method: 5030B

Parameter	Spike Amount (ug/L)	Result (ug/L)	Q	Dil	% Rec	% Rec Limit	Analysis Date
Trichloroethene	50	49		1	98	70-130	11/26/2016 0959
Trichlorofluoromethane	50	53		1	105	70-130	11/26/2016 0959
Vinyl chloride	50	46		1	91	70-130	11/26/2016 0959
Xylenes (total)	100	100		1	104	70-130	11/26/2016 0959

Surrogate	Q	% Rec	Acceptance Limit
Bromofluorobenzene		100	70-130
1,2-Dichloroethane-d4		88	70-130
Toluene-d8		100	70-130

PQL = Practical quantitation limit
ND = Not detected at or above the PQL
P = The RPD between two GC columns exceeds 40%
J = Estimated result < PQL and ≥ MDL
N = Recovery is out of criteria
+ = RPD is out of criteria

Where applicable, all soil sample analysis are reported on a dry weight basis unless flagged with a "A"

Note: Calculations are performed before rounding to avoid round-off errors in calculated results

Chain of Custody
and
Miscellaneous Documents

ENVIRONMENTAL SERVICES, INC.
ASSESSMENT & REMEDIAL SERVICES DIVISION

CHAIN OF CUSTODY RECORD

PAGE 1 OF 1

7 1st STREET SOUTH EXTENSION COLUMBIA, SOUTH CAROLINA 29209 PHONE 803-783-3311 FAX 803-783-2587

PROJECT #	PROJECT NAME
281.16	3244 Sumter St.

SAMPLERS SIGNATURE	LABORATORY UTILIZED
Andrew Neil	SHEALY

SAMPLE I.D.	DATE	TIME	COMP	GRAB	LOCATION	NUMBER OF CONTAINERS	MATRIX SOIL	MATRIX WATER	8260B
TMW-1	11/18	15:50		✓	TMW-1	3		✓	✓
TMW-2	↓	16:00		↓	TMW-2	3		✓	✓
TMW-3	✓	17:00		✓	TMW-3	3		✓	✓

REQUESTED PARAMETERS

RK21011

RELINQUISHED BY (SIGNATURE)	DATE	TIME	RECEIVED BY (SIGNATURE)	DATE	TIME
Andrew Neil	11/21	11:14	Ray Ong	11/21/16	11:14
RELINQUISHED BY (SIGNATURE)	DATE	TIME	RECEIVED BY (SIGNATURE)	DATE	TIME
Ray Ong	11-21	11:35	S. Gillett	11/21/16	1135

PROJECT MANAGER

P.O. NUMBER

REMARKS

T=3.7°C

Shealy Environmental Services, Inc
Document Number: MF001RC-06

Page 1 of 1
Effective Date: 11/18/2016
Expiry Date: 11/18/2021

Sample Receipt Checklist (SRC)

Client: ARM Cooler Inspected by/date: SJF 11/21/16 Lot #: 1621011

Means of receipt: ☑ SESI ☐ Client ☐ UPS ☐ FedEx ☐ Other

Yes ☐	No ☑		1. Were custody seals present on the cooler?
Yes ☐	No ☐	NA ☑	2. If custody seals were present, were they intact and unbroken?

pH strip ID: Cl strip ID:

Cooler ID/Original temperature upon receipt/Derived (corrected) temperature upon receipt:

13.5 / 13.7 °C / / °C / / °C / / °C

Method: ☑ Temperature Blank ☐ Against Bottles IR Gun ID: C IR Gun Correction Factor: 0.2 °C

Method of coolant: ☑ Wet Ice ☐ Blue Ice ☐ Dry Ice ☐ None

Yes ☐	No ☐	NA ☑	3. If temperature of any cooler exceeded 6.0°C, was Project Manager Notified? PM was Notified by: phone / email / face-to-face (circle one).
Yes ☐	No ☐	NA ☑	4. Is the commercial courier's packing slip attached to this form?
Yes ☑	No ☐		5. Were proper custody procedures (relinquished/received) followed?
Yes ☑	No ☐		6. Were sample IDs listed on the COC?
Yes ☑	No ☐		7. Were sample IDs listed on all sample containers?
Yes ☑	No ☐		8. Was collection date & time listed on the COC?
Yes ☑	No ☐		9. Was collection date & time listed on all sample containers?
Yes ☑	No ☐		10. Did all container label information (ID, date, time) agree with the COC?
Yes ☑	No ☐		11. Were tests to be performed listed on the COC?
Yes ☑	No ☐		12. Did all samples arrive in the proper containers for each test and/or in good condition (unbroken, lids on, etc.)?
Yes ☑	No ☐		13. Was adequate sample volume available?
Yes ☐	No ☑		14. Were all samples received within ½ the holding time or 48 hours, whichever comes first?
Yes ☐	No ☑	see dilution	15. Were any samples containers missing/excess (circle one) samples Not listed on COC?
Yes ☐	No ☑	NA ☐	16. Were bubbles present >"pea-size" (¼"or 6mm in diameter) in any VOA vials?
Yes ☐	No ☐	NA ☑	17. Were all DRO/metals/nutrient samples received at a pH of < 2?
Yes ☐	No ☐	NA ☑	18. Were all cyanide and/or sulfide samples received at a pH >12?
Yes ☐	No ☐	NA ☑	19. Were all applicable NH3/TKN/cyanide/phenol/BNA (<0.2mg/L) samples free of residual chlorine?
Yes ☐	No ☐	NA ☑	20. Were collection temperatures documented on the COC for NC samples?
Yes ☑	No ☐	NA ☐	21. Were client remarks/requests (i.e. requested dilutions, MS/MSD designations, etc...) correctly transcribed from the COC into the comment section in LIMS?
Yes ☐	No ☑		22. Was the quote number used taken from the container label?

Sample Preservation (Must be completed for any sample(s) incorrectly preserved or with headspace.)

Sample(s) _____ were received incorrectly preserved and were adjusted accordingly in sample receiving with _____ (H_2SO_4, HNO_3, HCl, NaOH) using SR # _____.

Sample(s) _____ were received with bubbles >6 mm in diameter.

Samples(s) _____ were received with TRC >0.2 mg/L (If #21 is No) and were adjusted accordingly in sample receiving with sodium thiosulfate ($Na_2S_2O_3$) with Shealy ID: _____.

SC Drinking Water Project Sample(s) pH verified to be < 2 by _____ Date: _____

Sample(s) _____ were Not received at a pH of < 2 and were adjusted accordingly using SR#

Sample labels applied by: SJF Verified by: _____ Date: 11/21/16

Comments: _____

Legend:
⊗ - Proposed Soil Boring/Temporary Monitoring Well Location

Project	Figure 2
Phase II ESA Proposal 2244 Sumter Street Columbia, South Carolina	Site Plan

Scale	Date	
No Scale	October 2016	ARM ENVIRONMENTAL SERVICES, INC.

ACKNOWLEDGMENT OF REQUEST FOR FINAL REVIEW

TO: Keenan Energy Company f/k/a Keenan Oil Co., Inc. Requestor/Permittee
W. Thomas Lavender, Attorney for Requestor

Sara P. Bazemore, Attorney for Department

FROM: Lisa Lucas Longshore, Clerk

RE: **Docket No. 17-RFR-12, Keenan Oil Co., Inc.**
Requirement of payment of deductible before access to SUPERB.

DATE: February 15, 2017

A Request for Final Review of the above-referenced decision was filed on February 8, 2017. A copy of the request is attached. The Board of Health and Environmental Control will notify you by mail as to whether it will conduct a final review conference in this matter.

The Board has 60 days from the date of receipt of a Request for Final Review to conduct a final review conference. If a final review conference is scheduled, all parties will be given at least 10 calendar days' written notice of the conference.

Procedures for final review conferences and requesting further review are provided in S.C. Code Section 44-1-60. Additional information on procedures will be provided to you after the Board decides whether to conduct a final review conference in this matter.

The above information is provided as a courtesy; parties are responsible for complying with all applicable legal requirements.

CERTIFICATE OF SERVICE

I, Lisa Lucas Longshore, Clerk of the SC Board of Health and Environmental Control and an employee of the South Carolina Department of Health and Environmental Control, hereby certify that I have this 15th day of February 2017, served the foregoing Acknowledgement of Request for Final Review and Notice of Procedures – Docket No. 17-RFR-12, upon all parties and/or counsel of record by electronic mail delivery as indicated below:

W. Thomas Lavender, Jr.
tlavender@nexsenpruet.com
Nexsen Pruet, LLC
Post Office Drawer 2426
Columbia, SC 29202

Joan Hartley
jhartley@nexsenpruet.com
Nexsen Pruet, LLC
Post Office Drawer 2426
Columbia, SC 29202

bazemosp
Sara P. Bazemore
SCDHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

Lisa Lucas Longshore, Clerk

February 15, 2017
Columbia, South Carolina

March 17, 2017

Via Email and U.S. Mail Certified 9214 8969 0099 9790 1407 7258 69
W. Thomas Lavender, Jr.
Joan W. Hartley
Nexsen Pruet
Post Office Drawer 2426
Columbia, SC 29202

Via Electronic Mail Delivery
Sara P. Bazemore
SCDHEC – Office of General Counsel
2600 Bull Street
Columbia, SC 29201

RE: **Docket No. 17-RFR-12, Keenan Energy Company f/k/a Keenan Oil Company, Inc.**

Dear Counsel of Record:

The South Carolina Board of Health and Environmental Control ("Board") will conduct a Final Review Conference during the Board meeting on Wednesday, April 5, 2017, at 10:00 a.m. in the Board Room (3420), of the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina, on the above referenced matter.

The Board has approved the following procedures to be used during the Final Review Conference:

- Swear all witnesses (if court reporter is present)
- Presentation by parties
  - Order of presentation:
    - DHEC Staff – 5 minutes
    - Requestor, Keenan Energy Group – 10 minutes
  - Rebuttal:
    - DHEC Staff – 10 minutes
    - Requestor, Keenan Energy Group – 5 minutes
- Parties may present evidence; rules of admissibility of evidence do not apply
- At any time during conference, officers conducting conference may request additional information and may question parties and anyone providing information
- Burden of proof is on Requestor(s)
- Presiding officer may impose time limits
- Conference is open to the public
- Officers may deliberate in closed session
- Officers may announce decision at conclusion of conference or may reserve consideration

If any party would like to have a transcript of the review conference, please notify, via e-mail, the Clerk of Board by Friday, March 31, 2017, so that arrangements can be made to have a reporter present for the conference. The parties requesting a court reporter will be responsible for payment of the court reporter.

Sincerely,

Lisa Lucas Longshore
Clerk