



STATE OF DELAWARE
**DEPARTMENT OF NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL**
RICHARDSON & ROBBINS BUILDING
89 KINGS HIGHWAY
DOVER, DELAWARE 19901

OFFICE OF THE
SECRETARY

PHONE
(302) 739-9000

**NOTICE OF ADMINISTRATIVE PENALTY ASSESSMENT
AND SECRETARY'S ORDER**

Pursuant to 7 *Del. C.* §§ 6005(b)(2) and (b)(3)

Order No. 2023-WH-0006

***PERSONALLY SERVED BY
AN ENVIRONMENTAL CRIMES
UNIT OFFICER***

Issued To:

Dr. Mathew George
Research and Development Director
Sepax Technologies, Inc.
5 Innovation Way, Suite 100
Newark, DE 19711

Registered Agent:

Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

Dear Dr. George:

The Secretary of the Department of Natural Resources and Environmental Control (“Department”) has found Sepax Technologies, Inc. (“Respondent” or “Sepax”) in violation of 7 *Del. C.* Chapters 60 and 63, and 7 DE Admin. Code § 1302, Delaware’s *Regulations Governing Hazardous Waste* (“DRGHW”). Accordingly, the Department is issuing this Notice of Administrative Penalty Assessment and Secretary’s Order, pursuant to 7 *Del. C.* § 6005.

BACKGROUND

Sepax operates a research and development facility located at 5 Innovation Way, Suite 100, Newark, Delaware 19711 ("facility"). During the operation of its facility, Sepax generates hazardous waste. As such, Respondent is subject to compliance inspections conducted by the Department's Compliance and Permitting Section ("CAPS"), pursuant to 7 DE Admin. Code § 1302.

On May 19, 2022, the Department conducted a compliance inspection of Sepax's facility. At the time of the inspection, Respondent was classified as a small quantity generator ("SQG")¹ of hazardous waste. The facility is assigned EPA ID number DER000503052. Based on the information gathered during the inspection, the Department found Respondent to be in violation of applicable state statutes and regulations governing the generation and management of hazardous waste.

The Department notified Respondent of the violations identified during the May 19, 2022, inspection by issuing to Respondent, Notice of Violation ("NOV") No. 22-HW-24, dated July 11, 2022. Respondent received the NOV on July 15, 2022. The NOV identified nine violations of DRGHW.

Respondent corrected three of the nine violations during the May 19, 2022, inspection. On May 31, 2022, Respondent submitted documentation to the Department demonstrating that it corrected another two of the nine violations. On July 20, 2022, Respondent submitted additional documentation to the Department in response to the remaining four violations cited in the NOV.

¹ Generators of more than 100 kilograms (220 pounds) but less than 1000 kilograms (2,200 pounds) of hazardous waste in any calendar month are small quantity generators (Delaware's *Regulations Governing Hazardous Waste*, 2021).

**FINDINGS OF FACT AND VIOLATION INCLUDING
REGULATORY REQUIREMENTS**

1. DRGHW Section 262.15(a)(5)(i) states:

“A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations or 1 kilogram (≈2.2 pounds) of solid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator(s) of the process generating the waste, without a permit or interim status and without complying with the requirements of Parts 124, 264 through 266, and 122 of these regulations, provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in §262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8). The conditions for exemption for satellite accumulation are:

- ...
(5) *A generator must mark or label its container with the following:*
(i) *The words ‘Hazardous Waste’; and...”*

On May 19, 2022, Department representatives observed one closed 5-gallon metal container in the SEC lab satellite accumulation area accumulating spent ethanol. In the Packing lab satellite accumulation area, Department representatives also observed one closed 5-gallon plastic carboy² accumulating spent solvents. Neither container was marked with the words, “Hazardous Waste.” Failure to mark a hazardous waste container in a satellite accumulation area with the words, “Hazardous Waste,” is a violation of DRGHW Section 262.15(a)(5)(i).

During the May 19, 2022, inspection, Respondent corrected this violation to the satisfaction of the Department representatives.

² A carboy is a rigid plastic container with a narrow neck typically used to transport liquid, chemicals or water.

2. DRGHW Section 262.15(a)(6) states:

“A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations or 1 kilogram (≈2.2 pounds) of solid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator(s) of the process generating the waste, without a permit or interim status and without complying with the requirements of Parts 124, 264 through 266, and 122 of these regulations, provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in §262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8). The conditions for exemption for satellite accumulation are:

*...
(6) A generator who accumulates either acute hazardous waste listed in §261.31 or §261.33(e) of these regulations or non-acute hazardous waste in excess of the amounts listed in paragraph (a) of this section at or near any point of generation must do the following:*

*(i) Immediately comply with the applicable central accumulation area regulations in §262.16(b) or §262.17(a), or
(ii) Immediately remove the excess from the satellite accumulation area to either:*

*(A) A central accumulation area operated in accordance with the applicable regulations in §262.16(b) or §262.17(a);
(B) An on-site interim status or permitted treatment, storage, or disposal facility, or
(C) An off-site designated facility.*

[Note: For the purposes of this paragraph, ‘immediately’ means within the same shift in which the 55-gallon limit was exceeded.]”

On May 19, 2022, Department representatives observed twenty (20) 5-gallon metal containers in the SEC lab satellite accumulation area. Each of the twenty 5-gallon metal containers were filled with spent ethanol waste. Of those twenty 5-gallon metal containers in the SEC lab satellite accumulation area, eight were accumulating inside a “flammable” cabinet and twelve were accumulating in-front of the “flammable” cabinet.

Accumulating twenty 5-gallon containers full of spent ethanol waste in the SEC lab satellite accumulation area equates to accumulating a total of 100 gallons of spent ethanol, a non-acute hazardous waste. Accumulating more than 55-gallons of non-acute hazardous waste in a satellite accumulation area is a violation of DRGHW Section 262.15(a)(6).

On May 31, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

3. DRGHW Section 262.15(a)(1) states:

“A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations or 1 kilogram (≈2.2 pounds) of solid acute hazardous waste listed in §261.31 or §261.33(e) of these regulations in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator(s) of the process generating the waste, without a permit or interim status and without complying with the requirements of Parts 124, 264 through 266, and 122 of these regulations, provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in §262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8). The conditions for exemption for satellite accumulation are:

(1) If a container holding hazardous waste is not in good condition, or if it begins to leak, the generator must immediately transfer the hazardous waste from this container to a container that is in good condition and does not leak, or immediately transfer and manage the waste in a central accumulation area operated in compliance with §262.16(b) or §262.17(a).”

On May 19, 2022, Department representatives observed free-flowing spent ethanol on the lid of one of the 5-gallon metal containers in the SEC lab satellite accumulation area. The free-flowing spent ethanol on the lid of the container appeared to be the result of the container having been overfilled by Respondent. Failure to immediately manage the free-flowing spent ethanol that was accumulating on the lid of the container due to the container being overfilled is a violation of DRGHW Section 262.15(a)(1).

During the May 19, 2022, inspection, Respondent corrected this violation to the satisfaction of the Department representatives by placing the free-flowing spent ethanol into a container.

4. DRGHW Section 262.16(b)(9)(ii)(A) states:

“Accumulation. The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

...
(9) Emergency procedures. The small quantity generator complies with the following conditions for those areas of the generator facility where hazardous waste is generated and accumulated:

...
(ii) The small quantity generator must post the following information next to telephones or in areas directly involved in the generation and accumulation of hazardous waste:

(A) The name and emergency telephone number of the emergency coordinator; ...”

On May 19, 2022, Department representatives observed two signs in the central accumulation area that listed emergency contact information. Both signs listed the emergency coordinator's telephone number but neglected to list the emergency coordinator's name. Failure to post the emergency coordinator's name in an area directly involved in the accumulation of hazardous waste is a violation of DRGHW Section 262.16(b)(9)(ii)(A).

On May 19, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

5. DRGHW Section 262.16(b) states:

"Accumulation. The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply: ..."

DRGHW Section 122.1(c) states:

"Scope of the hazardous waste permit requirement. DNREC requires a permit for the 'treatment', 'storage', and 'disposal' of any 'hazardous waste' as identified or listed in Part 261. The terms 'treatment', 'storage', 'disposal', and 'hazardous waste' are defined in Section 122.2."

On May 19, 2022, Department representatives observed three 5-gallon carboys of solvent waste that Respondent dated as having accumulation start dates of October 4, October 8, and November 16, 2021. Based on Respondent's self-dating of these three containers, at the time of the inspection, the containers had been accumulating for 225, 221, and 183 days, respectively. Accumulating hazardous waste for longer than the allowed 180-days accumulation time limit for small quantity generators of hazardous waste is a violation of DRGHW Section 262.16(b).

Furthermore, the 180-days accumulation time limit in DRGHW Section 262.16(b) is a condition to qualify for the exemption to the requirement to obtain a hazardous waste facility permit. Any operator failing to comply with the 180-days accumulation time limit condition is thereby operating a hazardous waste treatment, storage, or disposal facility in violation of DRGHW Section 122.1(c).

On July 20, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

6. DRGHW Section 262.16(b)(6)(i)(C) states:

"Accumulation. The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

...

(6) Labeling and marking of containers and tanks.

(i) Containers. A small quantity generator must mark or label its containers with the following:...

(C) The date upon which each period of accumulation begins clearly visible for inspection on each container."

On May 19, 2022, Department representatives observed one 5-gallon container of hazardous waste in the 180-day central accumulation area that was not marked with the accumulation start date. Failure to mark a hazardous waste container with an accumulation start date is a violation of DRGHW Section 262.16(b)(6)(i)(C).

On July 20, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

7. DRGHW Section 262.40(a) states:

“A generator must keep a copy of each manifest signed in accordance with §262.23(a) for three years or until he receives a signed copy from the designated facility which received the waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.”

On May 19, 2022, Department representatives reviewed Respondent's hazardous waste manifest records for three years preceding the date of inspection. Respondent was unable to provide designated facility signed copies of three hazardous waste manifests: Manifest Number 018499979JJK – shipped February 7, 2022, Manifest Number 018499954JJK – shipped September 29, 2021, and Manifests Number 018499874JJK – shipped April 19, 2021. Failure to maintain designated facility signed copies of hazardous waste manifests is a violation of DRGHW Section 262.40(a).

On May 31, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

8. DRGHW Section 262.16(b)(8)(vi)(B) states:

“Accumulation. The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

...
(8) Preparedness and prevention

...
(vi) Arrangements with local authorities

...
(B) A small quantity generator shall maintain records documenting written arrangements with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include documentation in the operating record that either confirms such arrangements actively exist or, in cases where no arrangements exist, confirms that attempts to make such arrangements were made. These records must be kept for a period of at least 3 years since last being applicable.”

On May 19, 2022, Respondent was unable to provide a record documenting its written emergency response arrangements with local emergency services for the period of three (3) years preceding the date of the inspection. Failure to maintain records documenting written emergency response arrangements with local emergency services is a violation of DRGHW Section 262.16(b)(8)(vi)(B).

On July 20, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

9. **DRGHW Section 262.16(b)(2)(v) states:**

“Accumulation. The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

...
(2) Accumulation of hazardous waste in containers

...
(v) Inspections. At least weekly, the small quantity generator must inspect central accumulation areas. The small quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (b)(2)(i) of this section for remedial action required if deterioration or leaks are detected. A written record of the inspections and remedial actions taken, if necessary, must be maintained onsite for a minimum of 3 years.”

On May 19, 2022, Department representatives performed a review of the inspection logs of the 180-day central accumulation area for the period between May 2019 and May 2022. During this three-year period, there were twenty-four (24) instances of Respondent failing to inspect and maintain a written record of the weekly 180-day central accumulation area inspection. During the inspection closing meeting, Department representatives requested that Respondent submit copies of the missing weekly inspection logs. In a May 19, 2022, email from Respondent sent after the inspection, a representative for Respondent explained that the twenty-four (24) aforementioned weekly inspection logs were misplaced. Respondent's failure to maintain records verifying weekly inspections of the central accumulation area is a violation of DRGHW Section 262.16(b)(2)(v)).

On July 20, 2022, Respondent submitted documentation to the Department demonstrating correction of this violation to the Department's satisfaction.

CONCLUSIONS

Based on the foregoing, the Department has concluded that Respondent has violated the above-cited statutory and regulatory provisions.

ASSESSMENT OF PENALTY

Pursuant to 7 *Del. C.* § 6005(b)(3), the Secretary may impose an administrative penalty of not more than \$10,000.00 for each day of violation detailed in this Order. This Order is written notice to Respondent, that, based upon its findings, the Department is assessing Respondent an administrative penalty for the violations identified in this Assessment and Order. In assessing the administrative penalty, 7 *Del. C.* § 6005(b)(3) instructs the Secretary to consider the following factors: (1) the nature, circumstances, extent, and gravity of the violation, or violations; (2) the ability of the violator to pay; (3) any prior history of such violations; (4) the degree of culpability; (5) the economic benefit or savings (if any) resulting from each violation; and (6) such other matters as justice may require. A brief discussion of these factors is set forth below.

1. The Nature, Circumstances, Extent and Gravity of the Violation, or Violations:

The nature, circumstances, extent, and gravity of the violations are significant. This Order identifies and describes nine (9) separate regulatory violations. Failing to ensure compliance with the regulatory requirements for the accumulation of hazardous waste, including labeling and dating of containers, properly managing waste leaking from a container due to overfilling, accumulation time limits, and maintenance of proper records are significant deviations from the statutory and regulatory requirements cited herein.

2. Respondents' Ability to Pay:

The record contains no information that Respondent lacks the ability to pay the administrative penalty assessed.

3. Prior History of Violations:

Respondent has had prior violations of some of the same or similar regulatory requirements. A NOV was previously issued to Respondent on December 9, 2016, citing Respondent for the following: (1) failing to properly label three (3) 55-gallon containers with "hazardous waste"; (2) failing to identify the accumulation start date on three (3) 55-gallon containers of hazardous waste; (3) failing to post Respondent's emergency coordinator's name; and (4) failing to ensure that the facility had six designated facility signed hazardous waste manifest copies. Said violations are identical or similar to Respondent's violations cited herein of DRGHW, Sections 262.15(a)(5)(i) (missing labels); 262.16(b)(6)(i)(C) (accumulation start date); 262.16(b)(9)(ii)(A) (emergency coordinator's name); and 262.40(a) (hazardous waste manifest records).

Respondent's history of similar violations supports imposition of a higher administrative penalty for the violations cited herein in order to deter Respondent from future violations.

4. Degree of Culpability:

The degree of culpability is significant, as Respondent was previously provided notice of many of these same regulatory violations and afforded the opportunity to come into voluntary compliance. In addition, had Respondent employed reasonable oversight measures as DRGHW require, these violations would not have occurred.

5. Economic Benefit or Savings Resulting from the Violation(s):

With respect to the economic benefit, the record contains no information that Respondent incurred any meaningful economic benefit from these violations, and thus this was not a factor in the administrative penalty assessment.

6. Such Other Matters as Justice May Require:

Lastly, considering such other matters as justice may require, the Secretary has determined that the penalty assessed is proportional to the violations cited herein and has been calculated to deter Respondent, and those similarly situated, from engaging in future violations.

Pursuant to *7 Del. C. § 6005(b)(3)*, this is written notice to Respondent that on the basis of the above findings and factors, an administrative penalty of \$10,000.00 is assessed for the violations identified in this Order.

Respondent shall submit one check to the Department in the amount of \$10,000.00 to pay the administrative penalty within 30 days from the receipt of this Assessment and Order. The checks shall be made payable to the "State of Delaware" and shall be directed to: Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.

PUBLIC HEARING AND APPEAL RIGHTS

This Assessment and Order affects Respondent's legal rights and is effective and final upon receipt by Respondent. Pursuant to Section 6008 of Title 7 of the Delaware Code, any person whose interest is substantially affected by this action of the Secretary may appeal to the Environmental Appeals Board within **20 days** of the receipt of the Assessment and Order. In the alternative, Respondent may, pursuant to *7 Del. C. § 6005(b)(3)*, request a public hearing on the Assessment and Order within **30 days** of receipt of the Assessment and Order. A public hearing pursuant to *7 Del. C. § 6005(b)(3)* would be conducted pursuant to *7 Del. C. § 6006*, and the Secretary's order following the hearing would be subject to appeal, pursuant to *7 Del. C. § 6008*, by any person substantially affected.

Respondent is further advised that the above assessed administrative penalty shall be due and owing within 30 days of Respondent's receipt of this Assessment and Order. In the event of nonpayment of the administrative penalty assessed above, and after Respondent has exhausted all legal appeals, if any, a civil action may be brought by the Secretary in Superior Court for collection of the administrative penalty, including interest, attorneys' fees and costs, and the validity, amount and appropriateness of such administrative penalty and/or costs shall **not** be subject to review pursuant to *7 Del. C. §§ 6005(b)(3) and (c)*.

To request a public hearing pursuant to *7 Del. C. § 6005(b)(3)*, please submit your request, in writing, to:

Department of Natural Resources and Environmental Control
Office of the Secretary
89 Kings Highway
Dover, DE 19901
Telephone: (302) 739-9000

To submit an appeal to the Environmental Appeals Board pursuant to *7 Del. C. § 6008*, you must file your written statement of appeal and submit a check, made payable to:

“Environmental Appeals Board,” for the \$50.00 filing fee, to:

Department of Natural Resources and Environmental Control
Office of the Secretary
Attn: Assistant to the Environmental Appeals Board
89 Kings Highway
Dover, DE 19901
Telephone: (302) 739-9000

For additional information on filing an appeal with the Environmental Appeals Board and what information you must include in your written statement of appeal, please refer to the Environmental Appeals Board Regulations, codified at *7 DE Admin. Code § 105*.

The Department, to the extent necessary, reserves the right to take additional enforcement actions regarding these and other violations by Respondent, including but not limited to one or more of the following: an action under 7 Del. C. § 6005(b)(1) seeking penalties for past violations, an action under 7 Del. C. § 6005(b)(2) seeking penalties for continuing violations, an action in the Court of Chancery pursuant to 7 Del. C. § 6005(b)(2) seeking a temporary restraining order or an injunction, and the imposition of civil penalties and recovery of the Department's costs and attorney's fees pursuant to 7 Del. C. §§ 6005(b)(3) & (c)(1). Nothing in this document shall be deemed to estop, or in any way preclude any additional enforcement action for these or any other violations, including administrative and civil penalties for each day of violation, or an action for the recovery of Department costs expended in abating these violations.

SECRETARY'S ORDER FOR COST RECOVERY

Pursuant to 7 Del. C. § 6005(c), Respondent is liable for all expenses incurred by the Department in abating the violations detailed in this Secretary's Order. "Such expenses shall include, but not be limited to, the costs of investigation, legal fees and assistance, public hearings, materials, equipment, human resources, contractual assistance and appropriate salary and overtime pay for all state employees involved in the effort notwithstanding merit system laws, regulations or rules to the contrary." (7 Del. C. § 6005(c)(1)).

Respondent is liable for \$1,473.25 in costs, which costs the Department has incurred **to date** in abating the violations detailed in this Secretary's Order. The Department has attached to this Secretary's Order a detailed billing of expenses detailing these costs. Respondent shall remit a check payable to the State of Delaware in the amount of \$1,473.25 within thirty (30) days of receipt of this Secretary's Order, to Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle, Delaware 19720.

In the event that Respondent appeals this Secretary's Order pursuant to 7 Del. C. § 6008 or requests a public hearing pursuant to 7 Del. C. § 6005(b)(3), or in the event Respondent fails to comply with this Secretary's Order, the Department will rescind the detailed billing attached to this Secretary's Order. The Department will issue Respondent a new detailed billing and Cost Recovery Order following exhaustion of Respondent's appeal rights that will include all additional recoverable costs incurred by the Department. Respondent is further advised that Respondent may challenge the Department's final detailed billing in accordance with 7 Del. C. § 6005(c)(2).

PRE-PAYMENT

Respondent may prepay the administrative penalty of **\$10,000.00** and the Department's costs in the amount of \$1,473.25 in the manner described in the attached "**Waiver of Statutory Right to A Hearing.**" **By doing so, Respondent waives its right to a hearing and the opportunity to appeal or contest this Secretary's Order and the Department's Cost Recovery.**

If you have any questions, please contact, or have your attorney contact Travis Groski, Deputy Attorney General, at (302) 395-2600.

4/17/23
Date


Shawn M. Garvin, Secretary

WAIVER OF STATUTORY RIGHT TO A HEARING

Sepax Technologies hereby waives its right to a public hearing and its opportunity to appeal or contest this Assessment and Order, and agrees to the following:

1. **Sepax Technologies** will pay the administrative penalty in the amount of \$10,000.00 by sending a check payable to the "State of Delaware" within 30 days of receipt of this Assessment and Order. The check shall be directed to Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle 19720.
2. **Sepax Technologies** will pay the Department's Costs in the amount of \$1,473.25 by sending a check payable to the "State of Delaware" within 30 days of receipt of this Assessment and Order. The check shall be directed to Travis Groski, Deputy Attorney General, 391 Lukens Drive, New Castle 19720.

Sepax Technologies

Date: _____

By: _____

Title: _____