



Florida Department of Environmental Protection

Central District
3319 Maguire Boulevard, Suite 232
Orlando, Florida 32803-3767

Charlie Crist
Governor

Jeff Kottkamp
Lt. Governor

Michael W. Sole
Secretary

Certified Mail

7007 0220 0004 1242 1626

Joe Doremus
President
Secure Waste Disposal, Inc.
P.O. Box 540417
Orlando, Florida 32854

OWL-HW-08-022

Orange County – HW
Secure Waste Disposal, Inc.
Warning Letter

Dear Mr. Doremus:

The purpose of this letter is to advise you of possible violations of law for which you may be responsible and to seek your cooperation in resolving the matter. During a file review on March 27, 2008, the Department received information that Secure Waste Disposal, Inc., located at 6357 All American Boulevard, Orlando, was transporting hazardous waste from a generator location and disposing of the waste at a facility not permitted to accept hazardous waste. The purpose of this file review, conducted under the authority of Section 403.091, Florida Statutes, and Chapter 403, Part IV, Florida Statutes, was to determine the compliance status of your facility with Title 40 Code of Federal Regulations (CFR) 260-268, adopted in Florida Administrative Code Chapter 62-730, and other Florida laws relating to hazardous waste.

During the file review, Department personnel identified possible violations of Florida Statutes and Rules regarding hazardous waste. These violations are set forth in the "Open Citations" section of the attached inspection report.

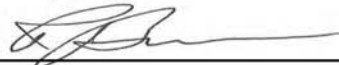
The activities identified during the Department's file review and any activity at your facility that may be contributing to violations of the above described statutes and rules should be ceased immediately.

The Department has calculated penalties for the violations addressed above. The penalty work sheets are enclosed. The penalty amounts were calculated in accordance with the U.S. EPA RCRA Civil Penalty Policy and the Department's Guidelines for Characterizing RCRA Violations. A copy of the documents is available upon request.

Please contact John White, Hazardous Waste Section, by telephone at (407) 893-3323 or by e-mail at john.white@floridadep.net within 10 days of receipt of this letter to schedule an informal conference concerning resolution of this matter. The Department is interested in reviewing any facts you may have that will assist in determining whether any violations have occurred and whether any penalties are appropriate. You may bring anyone with you to the meeting that you feel could help resolve this matter.

This Warning Letter is part of an agency investigation preliminary to agency action in accordance with Section 120.57(4), Florida Statutes. The Department looks forward to your cooperation in completing the investigation and resolution of this matter.

Sincerely,



For Vivian F. Garfein
Director, Central District

September 24, 2008
Date

VFG/lb/jw

Attachments: Inspection Report
Penalty Calculation

cc: Debby Valin, FDEP

PENALTY COMPUTATION WORKSHEET

Violator's Name: Secure Waste Disposal, Inc.

Identify Violator's Facility: 6357 All American Blvd, Orlando, Orange County, Florida

Name of Department Staff Responsible for the Penalty Computations: John White

Date: September 15, 2008

	Violation Type	Manual Guide	Potential for Harm	Extent of Deviation	Matrix Range	Multi Event	Economic Benefit	Total
a.	263.11(a) - Notification	HW 6.3	Major	Major	\$32,500 - \$25,791		---	\$25,791
b.	263.20 - Manifests	HW 7.1	Moderate	Major	\$14,184 - \$10,316	\$12,900	---	\$23,216
TOTAL								\$49,007

Total Penalties for all Violations:

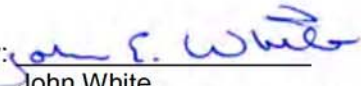
\$49,007.00


A review of shipping papers used by Leesburg Regional Medical Center identified twenty six shipments of chemotherapy wastes from Leesburg Regional Medical Center during the period of July 19, 2007 and February 11, 2008. The average shipment consisted of two to three 17-gallon containers.

The multi-event matrix (found in the RCRA EPA Penalty Policy) for Moderate Potential for Harm and Major Extent of Deviation is \$516 - \$2,837. For this violation the lower end of the matrix was selected. $\$516 \times 25 (26 \text{ events} - 1) = \$12,900$.

40 CFR 263.11(a) – Joe Doremus, as the controlling officer of a medical waste transporter, has been cited twice before for failure to notify the Department of hazardous waste transportation activities. Therefore, a Major Potential for Harm and a Major Extent of Deviation from the rules is warranted. The low end of the penalty matrix was selected for this violation.

40 CFR 263.20 – Shipping papers, as opposed to hazardous waste manifests, were used to document the transport of hazardous chemotherapy wastes from Leesburg Regional Medical Center. The waste was disposed of at Covanta Huntsville, located in Huntsville, Alabama. This facility is not permitted to manage hazardous waste. Therefore, a Moderate Potential for Harm and a Major Extent of Deviation from the rules is warranted. The low end of the penalty matrix was selected for this violation.

Penalties Prepared By: 
John White
Environmental Specialist


For Vivian F. Garfein
Director, Central District

September 15, 2008
Date

September 24, 2008
Date



Florida Department of Environmental Protection

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HAZARDOUS WASTE INSPECTION REPORT

1. **INSPECTION TYPE:** ☒ Routine ☐ Complaint ☐ Follow-Up ☐ Permitting ☒ File Review

FACILITY NAME Secure Waste Disposal Inc EPA ID # No EPA ID

STREET ADDRESS 6357 All American Blvd, Orlando, Florida 32810

MAILING ADDRESS PO Box 540417, Orlando, Florida 32854

COUNTY Orange PHONE 407-850-1010 DATE 03/27/08 TIME

NOTIFIED AS: ☒ N/A

- ☐ Non Handler
- ☐ CESQG (<100 kg/mo.)
- ☐ SQG (100-1000 kg/mo.)
- ☐ Generator (>1000 kg/mo.)
- ☐ Transporter
- ☐ Transfer Facility
- ☐ Interim Status TSD Facility
- ☐ TSD Facility
- Unit Type(s):
- ☐ Exempt Treatment Facility
- ☐ Used Oil: Generator

CURRENT STATUS:

- ☐ Non Handler
- ☐ CESQG (<100 kg/mo.)
- ☐ SQG (100-1000 kg/mo.)
- ☐ Generator (>1000 kg/mo.)
- ☒ Transporter
- ☐ Transfer Facility
- ☐ Interim Status TSD Facility
- ☐ TSD Facility
- Unit Type(s):
- ☐ Exempt Treatment Facility
- ☐ Used Oil: Generator

2. **APPLICABLE REGULATIONS:**

- | | | | |
|---------------------------------------|--------------------------------------|--|---|
| <input type="checkbox"/> 40 CFR 261.5 | <input type="checkbox"/> 40 CFR 262 | <input checked="" type="checkbox"/> 40 CFR 263 | <input type="checkbox"/> 40 CFR 264 |
| <input type="checkbox"/> 40 CFR 265 | <input type="checkbox"/> 40 CFR 266 | <input type="checkbox"/> 40 CFR 268 | <input type="checkbox"/> 40 CFR 273 |
| <input type="checkbox"/> 40 CFR 279 | <input type="checkbox"/> 62-710, FAC | <input type="checkbox"/> 62-737, FAC | <input checked="" type="checkbox"/> 62-730, FAC |

3. **RESPONSIBLE OFFICIAL(s):**

Joe Doremus, President

4. **INSPECTION PARTICIPANTS:**

John White – FDEP
Janine Kraemer - FDEP

5. **SIC Code:** 4214 – Local Trucking with Storage

6. **TYPE OF OWNERSHIP:** Private Federal State County Municipal

7. **LATITUDE/LONGITUDE:** 28° 36' 59.4" / 81° 25' 2.7"

8. **PERMITS:** None

9. **Introduction:**

On November 14, 2007, John White and Janine Kraemer, Florida Department of Environmental Protection, inspected Secure Waste Disposal, Inc. in response to a complaint that the facility was accepting hazardous waste generated by hospitals for disposal as medical waste. Secure Waste Disposal, Inc. (SWDI), located at 6357 All American Boulevard, Orlando, is a transporter of medical waste and waste paper containing confidential documents. Inspectors were not able to verify the allegations at the time of the inspection.

On March 27, 2008, the Department received information that SWDI was transporting hazardous waste from Leesburg Regional Medical Center (LRMC) without the use of a hazardous waste manifest and disposing of the waste at a facility not permitted to manage hazardous waste.

In a Request for Information letter issued May 7, 2008, the Department requested information regarding the disposal facility used for management of chemotherapy waste, the names and addresses of all Florida companies SWDI has, or had, contracts with to manage chemotherapy and/or pharmaceutical waste, and a description of the company's activities at its current location.

In its response to the Request for Information, dated May 30, 2008, SWDI identifies Covanta Huntsville, located in Huntsville, Alabama, as the disposal location for chemotherapy waste transported by the company. According to Secure Waste Disposal, Inc. the only contract for management of chemotherapy and pharmaceutical waste held by the company was with LRMC.

Processes conducted by SWDI at 6357 All American Boulevard include confidential document shredding and storing biomedical waste until disposal. SWDI has not notified the Department of its activities as a transporter of either hazardous waste or universal pharmaceutical waste.

10. **Inspection History:**

Joe Doremus, President of Secure Waste Disposal, Inc. formerly operated Bio-Waste Industries, Inc. Bio-Waste Industries, Inc. was sold in 2002 and Mr. Doremus' was not involved in managing medical waste again until 2007.

During an inspection on July 25, 2000, Bio-Waste Industries, Inc. was found to be operating as a hazardous waste transporter without having notified the Department of its hazardous waste activities and without providing proof of adequate insurance. The case was settled through issuance of a Short Form Consent Order, 01-0557, on April 30, 2001, including assessment of \$3,700 in costs and penalties

During an inspection on May 8, 1997, Bio-Waste Industries, Inc. was found to be operating as a hazardous waste transporter without having notified the Department of its hazardous waste activities and without providing proof of adequate insurance. The case was settled through issuance of a Short Form

Consent Order, 98-0272, on October 22, 1998, including assessment of \$31,600 in costs and penalties.

11. **Process Description:**

SWDI provides document shredding services and, as of June 2007, biomedical waste disposal services. They do not open or repackage containers of chemotherapy waste. The containers are shipped to Covanta, located in Huntsville, Alabama. A company called Bio-Tech, located in Melbourne, Florida, was originally taking biomedical waste for treatment in an autoclave.

SWDI's two largest customers for waste pharmaceuticals are Nephron Pharmaceutical and Hill Pharmaceutical. A Supplemental Waste Tracking Form provided to Secure Waste Disposal, Inc. by Covanta documents which non-hazardous wastes the Covanta facilities in Huntsville, Alabama, and in Okahumpka, Florida, can accept. Neither Covanta facility is permitted to accept hazardous (chemotherapy) waste. According to Mr. Doremus in a statement made during the November 14, 2007 inspection, waste picked up from Leesburg Regional Medical Center included chemotherapy waste contaminated tubing and empty containers, but no liquid waste.

12. **File Review:**

On February 13, 2008, the Department inspected Leesburg Regional Medical Center (LRMC), Leesburg, Florida. During the inspection, it was found LRMC was sorting chemotherapy waste into "bulk" waste, containing liquids, and "trace" waste, containing empty containers, gowns, gloves, etc. As part of the inspection on March 25, 2008, the Department requested information from LRMC regarding the types of chemotherapy drugs administered. On March 26, 2008, the Department received the following information from LRMC:

"We looked at our Chemotherapy usage from 3/1/07 through 2/29/08. Here are the results of what Chemotherapy products were used during that period. Cytarabine, Bleomycin, Fludarabine, Fluorouracil, Methotrexate, **Mitomycin**, **Cyclophosphamide**, Vincristine, Carboplatin, Cisplatin, Paclitaxel, Vinblastine, **Etoposide**, **Carmustine**, Bicalutamide, Ifosfamide, Anastrozole, Dacarbazine, Flutamide, Topotecan, Irinotecan, Mercaptopurine, Gemcitabine, Letrozole, Vinorelbine, Rituximab, Hydroxyurea, Capecitabine, Doxorubicin, Docetaxel, Trastuzumab, Megestrol, Exemestane, Oxaliplatin, Bevacizumab, Cetuximab, Azacitidine, Pemetrexed, Epirubicin, Mitotane, Pentostatin, Bortezomib."

Those items with the bold emphasis added are identified as either "U-Listed" hazardous waste or "D001" ignitable waste in 40 CFR Parts 261 Subparts C and D. In a Hazardous Waste Program Guidance Document, G559, dated July 22, 1996, the Department determined that all antineoplastic agents would be regulated as hazardous waste in the State of Florida because of the similarity in chemical structure, mode of action, and toxicity.

On June 30, 2007, SWDI entered into a "Chemotherapy and Hazardous Pharmaceutical Waste Service Agreement" with Leesburg Regional Medical Center. A copy of the agreement is included as Exhibit 1. Item number 3 of the agreement includes the statements "Customer shall not deliver SWDI hazardous wastes or materials" and "This Agreement does not require SWDI to inspect any wastes provided by Customer to SWDI for removal to ensure compliance with the Agreement and applicable law." Secure Waste Disposal, Inc. made no effort to ensure the company did not transport hazardous waste from LRMC considering the customer, LRMC, was segregating chemotherapy wastes into "Bulk" containers, which included liquid wastes, and "Trace" containers, which included empty containers. A review of shipping papers used by Leesburg Regional Medical Center identified twenty six shipments of chemotherapy wastes from Leesburg Regional Medical Center were made by SWDI during the period of July 19, 2007 and February 11, 2008. The average shipment consisted of two to three 17-gallon containers.

13. **Potential Non-Compliance Items and Recommended Corrective Actions:**

- a) Regulation: 40 CFR 263.11 / 62-730.171(3) - Notification
A transporter must not transport hazardous wastes without having received an EPA identification number from the Administrator.

The owner or operator of a transfer facility which stores manifested shipments of hazardous waste for more than 24 hours but 10 days or less shall notify the Department on the Transfer Facility Notification Form. The owner or operator of a new facility shall submit a notification form at least 30 days before the storage of hazardous waste is to begin.

Secure Waste Disposal, Inc. operated as a transporter of hazardous waste and as a hazardous waste transfer facility managing hazardous waste generated by Leesburg Regional Medical Center. The hazardous waste was stored by Secure Waste Disposal, Inc. for greater than 10 days without authorization at a location that, due to the proximity of homes, could not be approved for this activity. Secure Waste Disposal, Inc. did not notify the Department of its activities and did not provide proof of adequate insurance for these activities.

Recommended Corrective Action

Secure Waste Disposal, Inc. must cease all transportation related activities related to hazardous waste or waste pharmaceuticals.

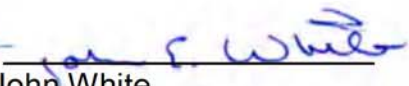
- b) Regulation: 40 CFR 263.20 – Manifest
A transporter may not accept hazardous waste from a generator unless the transporter is also provided with a manifest signed in accordance with the requirements of §262.23.

Recommended Corrective Action

Secure Waste Disposal, Inc. transported at least twenty six separate shipments of hazardous waste from Leesburg Regional Medical Center without the use of a hazardous waste manifest. As a result, the hazardous waste was transported to a waste disposal facility not permitted to accept such waste.

14 **Conclusion:**

Secure Waste Disposal, Inc. operated as a hazardous waste transporter and transfer facility and was not in compliance at the time of this file review.

Report Prepared By: 
John White
Environmental Specialist

Report Reviewed By: 
Lu Burson
Environmental Manager

jw