



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

7006 0810 0000 0865 5747

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

OCD-HW-08-393

Orange County – HW
No EPA ID
Secure Waste Disposal, Inc.
Proposed Short Form Consent Order and Revised Penalties

Dear Mr. Doremus:

Department staff contacted Leesburg Regional Medical Center (LRMC) in an effort to identify the types of chemotherapy waste included in the twenty-six shipments transported by Secure Waste Disposal, Inc. from LRMC. LRMC was contacted in response to questions you raised during an informal meeting on October 14, 2008. Other than to indicate liquid chemotherapy wastes were shipped, LRMC staff were not able to provide any additional information regarding the specific chemicals and how much might have been included in each shipment.

In a guidance memo dated July 22, 1996 (Attachment 1), the Department stated its intent to regulate the disposal of all antineoplastic agents as RCRA regulated toxic waste because of the similarity in chemical structure, mode of action, and toxicity. These agents clearly meet the definition of hazardous waste as identified in 403.703(13), Florida Statutes, which states:

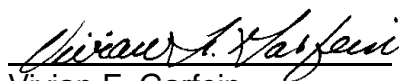
"hazardous waste" means solid waste, or a combination of solid wastes, which, because of its quantity, concentration, or physical, chemical, or infectious characteristics, may cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness or may pose a substantial present or potential hazard to human health or the environment when improperly transported, disposed of, stored, treated, or otherwise managed.

As the owner/operator of a transportation company, you have been cited twice before by the Department for the improper transportation of hazardous waste. Attached is a copy of a telephone conversation log (Attachment 2) created by Mr. William Kappler of the Department on November 30, 2000, documenting his discussion with you regarding issues related to transportation of chemotherapy waste.

LPMC was the only company for which hazardous wastes were transported and shipping papers documenting the movement of waste were maintained. In an effort to resolve these issues the assessed civil penalties have been recalculated and reduced based on the specific circumstances of your situation. The assessed civil penalties are \$8,382.00. Attached is a proposed Short Form Consent Order (SFCO). If the proposed Order is acceptable, please sign and return the document. If it is not acceptable, please provide a written response within twenty days of your receipt of this letter. If you do not respond within 20 days, the Department will assume you are not interested in resolving the matter and will proceed accordingly.

If you have any questions, please contact John White, Hazardous Waste Section, by e-mail at john.white@dep.state.fl.us or by telephone at (407) 893-3323.

Sincerely,


Vivian F. Garfein
Director, Central District

January 5, 2009
Date

VFG/lb/jw

Attachments:

1. Guidance memo dated July 22, 1996
2. Telephone Conversation Log dated November 30, 2000
3. Proposed SFCO



Florida Department of Environmental Protection

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January 5, 2009

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7006 0810 0000 0865 5747

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

OCD-HW-08-393

SUBJECT: Proposed Settlement of Secure Waste Disposal, Inc.
OGC File No.: 08-2874

Dear Mr. Doremus:

The purpose of this letter is to complete the resolution of the matter previously identified by the Department in the Warning Letter dated September 24, 2008, a copy of which is attached. The corrective actions required to bring your facility into compliance have been performed. The Department finds that you are in violation of the rules and statutes cited in the attached Warning Letter. In order to resolve the matters identified in the attached Warning Letter, you are assessed civil penalties in the amount of \$8,382.00, along with \$ 250.00 to reimburse the Department costs, for a total of \$8,632.00.

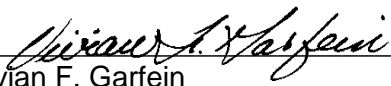
The civil penalties are apportioned as follows: \$1,934.00 for violation of 403.727(1)(f), Florida Statutes / 40 CFR 263.11(a) – Notification; and \$6,448.00 for violation of 403.727(1)(a), Florida Statutes / 40 CFR 263.20 – Manifests.

The Department acknowledges that the payment of these civil penalties by you does not constitute an admission of liability. This payment must be made payable to the Department of Environmental Protection by cashier's check or money and shall include the OGC File Number assigned above (08-2874) and the notation "Ecosystems Management and Restoration Trust Fund." Payment shall be sent to the Department of Environmental Protection, 3319 Maguire Boulevard, Orlando, Florida 32803, within 30 days of your signing this letter.

Your signing this letter constitutes your acceptance of the Department's offer to resolve this matter on these terms. If you elect to sign this letter, please return it to the Department at the address indicated above. The Department will then countersign the letter and file it with the Clerk of the Department. When the signed letter is filed with the Clerk, the letter shall constitute final agency action of the Department which shall be enforceable pursuant to Sections 120.69 and 403.121, Florida Statutes.

If you do not sign and return this letter to the Department at the District address by January 15, 2009, the Department will assume that you are not interested in settling this matter on the above described terms, and will proceed accordingly. None of your rights or substantial interests are determined by this letter unless you sign it and it is filed with the Department Clerk.

Sincerely,



Vivian F. Garfein
Director, Central District

FOR THE RESPONDENTS:

I, _____ on behalf of _____, **HEREBY
ACCEPT THE TERMS OF THE SETTLEMENT OFFER IDENTIFIED ABOVE.**

By: _____

Date: _____

FOR DEPARTMENT USE ONLY

DONE AND ENTERED this _____ day of _____, 2009.

STATE OF FLORIDA DEPARTMENT
OF ENVIRONMENTAL PROTECTION

Director of District Management

FILING AND ACKNOWLEDGMENT

FILED, on this date, pursuant to §120.52, Florida Statutes,
With the designated Department Clerk, receipt of which is hereby
Acknowledged.

Clerk

Date

Attachment: Warning Letter 08-022

Copies furnished to:
Lea Crandall, Agency Clerk, Mail Station 35

NOTICE OF RIGHTS

Persons who are not parties to this Consent Order but whose substantial interests are affected by this Consent Order have a right, pursuant to Sections 120.569 and 120.57, Florida Statutes, to petition for an administrative hearing on it. The Petition must contain the information set forth below and must be filed (received) at the Department's Office of General Counsel, 3900 Commonwealth Boulevard, MS-35, Tallahassee, Florida 32399-3000, within 21 days of receipt of this notice. A copy of the Petition must also be mailed at the time of filing to the District Office named above at the address indicated. Failure to file a petition within the 21 days constitutes a waiver of any right such person has to an administrative hearing pursuant to Sections 120.569 and 120.57, Florida Statutes.

The petition shall contain the following information:

(a) The Department's Consent Order identification number and the county in which the subject matter or activity is located; (b) The name, address, and telephone number of each petitioner; the name, address, and telephone number of the petitioner's representative, if any, which shall be the address for service purposes during the course of the proceeding; (c) An explanation of how the petitioner's substantial interests will be affected by the Consent Order; (d) A statement of when and how the petitioner received notice of the Consent Order; (e) A statement of all material facts disputed by petitioner, if any; (f) A statement of the specific facts the petitioner contends warrant reversal or modification of the Consent Order; (g) A statement of which rules or statutes the petitioner contends require reversal or modification of the Consent Order; and (h) A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the Department to take with respect to the Consent Order.

If a petition is filed, the administrative hearing process is designed to formulate agency action. Accordingly, the Department's final action may be different from the position taken by it in this Notice. Persons whose substantial interests will be affected by any decision of the Department with regard to the subject Consent Order have the right to petition to become a party to the proceeding. The petition must conform to the requirements specified above and be filed (received) within 21 days of receipt of this notice in the Office of General Counsel at the above address of the Department. Failure to petition within the allowed time frame constitutes a waiver of any right such person has to request a hearing under Sections 120.569 and 120.57, Florida Statutes, and to participate as a party to this proceeding. Any subsequent intervention will only be at the approval of the presiding officer upon motion filed pursuant to Rule 28-106.205, Florida Administrative Code.

Mediation under Section 120.573, Florida Statutes, is not available in this proceeding.

PENALTY COMPUTATION WORKSHEET

Violator's Name: Secure Waste Disposal, Inc.

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

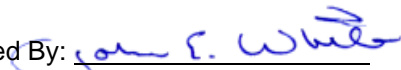
Name of Department Staff Responsible for the Penalty Computations: John White

Date: December 11, 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	Minor	Major	\$3,868 - \$1,934		---	\$1,934
b.	263.20 - Manifests	HW 7.1	Moderate	Moderate	\$10,315 - \$6,448		---	\$6,448
TOTAL								\$8,382

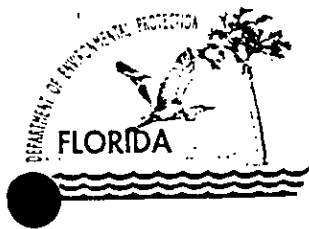
Total Penalties for all Violations: \$8,382.00

Economic Benefit and Multi-Day penalties were not calculated for these violations.

Penalties Prepared By: 
 John White
 Environmental Specialist

December 11, 2008
 Date

jw



Department of Environmental Protection

G 559

Lawton Chiles
Governor

Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Virginia B. Wetherell
Secretary

July 22, 1996

Mr. Ed Golding
Biomedical Waste Coordinator
HRS
2639 N. Monroe Street
Suite 126-A
Tallahassee, FL 32303

RE: CESQGs Handling Biomedical Hazardous Waste

Dear Mr. Ed Golding:

This letter is in response to your telephone conversation with Mr. Mike Redig of our section requesting information about conditionally exempt small quantity generators (CESQG) who handle biomedical hazardous wastes.

Pursuant to Florida Administrative Code (F.A.C.) Rule Chapter 62-296.401(4)(e)(8), hazardous waste may not be burned in a biological waste incinerator unless the incinerator has been issued a hazardous waste permit by the Department or the waste is of such quantity to be exempt in accordance with Chapter 62-730, F.A.C.

Currently, seven antineoplastic agents or chemotherapy drugs are listed in 40 CFR Part 261.33(f) (the U-list). Even though these agents represent only a small percentage of all antineoplastic agents, the Department has decided to regulate the disposal of all antineoplastic agents as RCRA regulated toxic waste because of the similarity in chemical structure, mode of action, and toxicity. The following are the human antineoplastic drugs or chemotherapy drugs defined by EPA as hazardous waste:

- | | |
|---------------------|------|
| 1. Chlorambucil | U035 |
| 2. Cyclophosphamide | U058 |
| 3. Daunomycin | U059 |
| 4. Melphalan | U150 |
| 5. Mitomycin C | U010 |
| 6. Streptozotocin | U206 |
| 7. Uracil mustard | U237 |

96TAL016.DOC

"Protect, Conserve and Manage Florida's Environment and Natural Resources"

Printed on recycled paper.

The chemotherapy drugs that are not listed hazardous wastes are not regulated by EPA. The unused, discarded, off-specification species, container residues, and spill residues of these chemicals are hazardous waste and should be managed properly under RCRA Subtitle C Regulations. Under the following circumstances these chemicals are excluded from RCRA regulations: 1) if the container of these hazardous wastes meet the criteria of an "Empty Container"; 2) if the waste is generated by a conditionally exempt small quantity generator (CESQG).

Under EPA regulations, certain empty containers (and the residues therein) are not subject to hazardous waste regulations. Pursuant to 40 CFR Part 261.7, a container or an inner liner removed from a container that has held any hazardous waste is empty and is not regulated as a hazardous waste if :

- All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container (e.g., pouring, pumping, and aspirating), and
- No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, or
- No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 110 gallons in size, or
- No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than or equal to 110 gallons in size.

The container or an inner liner removed from a container that has held an acute hazardous waste is empty if:

- The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;
- The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or
- The case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

Pursuant to 40 CFR Part 261.5, if a facility generates less than 100 kilograms (220 lbs) of hazardous waste per month or less than 1 kilogram (2.2 lbs) of an acute hazardous waste per month, and no more than 100 kilograms (220 lbs) of contaminated material from the cleanup of a spillage of acute hazardous waste, then the facility is considered a conditionally exempt small quantity generator (CESQG) and it is not subject to RCRA regulations. The CESQG, however, must still:

- Identify the waste to determine whether it is a hazardous waste (40 CFR Part 262.11).
- Can not accumulate at any given time more than 1000 kilograms (2200 lbs) of hazardous waste, more than 1 kilogram (2.2 lbs) of an acute hazardous waste, and more than 100 kilograms (220 lbs) of contaminated material from the cleanup of a spillage of acute hazardous waste on-site.
- Ensure delivery of hazardous waste to an appropriate off-site treatment, storage, disposal facility (TSDF) or a recycling facility.
- Document delivery of its hazardous waste through written receipts which are retained for at least three years.
- The hazardous waste must be recycled within 24 hours at recycling facility from the time of arrival, unless they have a storage permit. The waste generated from recycling operations must be managed properly.

Although the CESQGs are exempt from RCRA regulations, pursuant to 40 CFR 262.31, before transporting or offering hazardous waste for transportation off-site, a generator must label each package in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR Part 172. Also, our section always encourages the CESQGs to label or mark each container of hazardous waste clearly with the word "Hazardous Waste" during the accumulation on-site and during transportation to ensure safe transportation of hazardous waste.

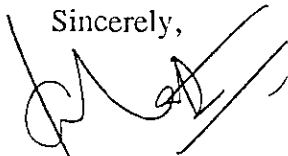
Acutely toxic hazardous waste is any hazardous waste with an EPA Waste Code beginning with the letter "P", or any of the following "F" codes: F020, F021, F022, F023, F026, and F027. These wastes are subject to stringent quantity standards for accumulation and generation.

Mr. Ed Golding
HRS
Page four

Attached are a copy of the F.A.C. Chapter 62-296.401, a copy of the USEPA letter dated June 16, 1987, a copy of the 40 CFR Part 261.5, and a copy of the list of the acute hazardous wastes.

If you have any questions please call Mike Redig, Subra Putcha or Mahnaz Massoudi in the Hazardous Waste Regulation Section at (904) 488-0300 or for further information, contact Edward Rau, at National Institutes of Health (NIH) at (301) 496 -7990.

Sincerely,



Satish Kastury
Environmental Administrator
Hazardous Waste Regulation Section

SK/mm

CC: Subra Putcha, FDEP-HWR
Susan Horlick, FDEP-HWR
Diana Coleman, FDEP-OGC
District Waste Program Administrators
District Technical Committee Members
Tom Moore, HSEH - Environmental Health Programs
Reading File

+

TELEPHONE CONVERSATION LOG

To

From: Joe Doremus – Bio-Waste Industries

Date: 11/30/00 **Time:** 10:05 am

Case Name: Bio-Waste Industries

Phone #:

I received a call from Joe Doremus concerning the proper transportation and handling of chemotherapy I.V. bags and tubing. Mr. Doremus asked me questions concerning U and P-listed chemotherapy I.V. bags generated from oncology medical facilities and how they would be regulated after they have been used. Mr. Doremus pointed out to me that these bags are not normally contaminated with bodily fluids.

I told Mr. Doremus that I.V. bags and tubing that contained characteristic and U-listed chemotherapy drugs are not hazardous waste if they are RCRA empty. I recommended to him that he should determine that the bags are empty before transporting.

I.V. bags and tubing that contained P-listed chemotherapy drugs should be managed as hazardous waste, unless triple rinsed.

We did not discuss unused chemotherapy I.V. bags.

WK



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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.

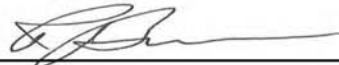
The activities identified during the Department's file review and any activity at your facility that may be contributing to violations of the above described statutes and rules should be ceased immediately.

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
John White
Environmental Specialist

[Signature]
For Vivian F. Garfein
Director, Central District

September 15, 2008
Date

September 24, 2008
Date



Florida Department of Environmental Protection

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

Charlie Crist
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Lt. Governor

Michael W. Sole
Secretary

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.

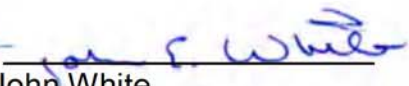
- b) Regulation: 40 CFR 263.20 – Manifest
A transporter may not accept hazardous waste from a generator unless the transporter is also provided with a manifest signed in accordance with the requirements of §262.23.

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.

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