Texas Commission on Environmental Quality Investigation Report

Stericycle, Inc. CN600362693

STERICYCLE

RN102942885

Investigation #915746

Incident #

Investigator:

CHRISTOPHER WIATREK

Site Classification

MEDICAL WASTE AUTOCLAVE

Conducted:

05/05/2011 -- 05/12/2011

NAIC Code: 562211

SIC Code: 4953

Program(s):

MEDICAL WASTE

MUNICIPAL SOLID WASTE

PROCESSING

Investigation Type: Compliance Investigation

Location: MEDICAL WASTE

TRANSPORTER

Additional ID(s):

2260A 2260

Address: 2607 HIGHWAY 21 W;

Activity Type:

REGION 11 - AUSTIN

DALE, TX 78616

VIXCEI - CEI of facilities (excluding Types VII & VIII) for

compliance with Chapter 330 or 332, as applicable

Principal(s):

Role

Name

RESPONDENT

STERICYCLE INC

Contact(s):

Role

Title

Name

Phone Work

Work

(512) 243-0032

(210) 648-9592

Participated in Investigation Participated in Investigation FACILITY MANAGER

MR JOEL B BARR MR MARK TRIPLETT

ENVIRONMENTAL MANAGER -

FACILITY MANAGER

Work (504) 220-9732

SOUTHWEST

JOHN EARNHARDT

Participated in Investigation Other Staff Member(s):

Role

Name

Supervisor **QA** Reviewer **BARRY KALDA** BEN MILFORD

Associated Check List

Checklist Name

Unit Name

MSW GENERIC OTHER ISSUES OR VIOLATIONS

Stericycle

Investigation Comments:

INTRODUCTION

This investigation was conducted in response to the Texas Commission on Environmental Quality (TCEQ) Austin Region's investigation findings at Whole Woman's Health of Austin, LLC (Investigation No. 912801).

On May 1, 2011, I contacted Mr. Joel Barr, Stericycle Inc. Facility Manager, and informed him of

Page 2 of 5

my intent to conduct an onsite investigation at Stericycle Inc.'s autoclave located in Dale, Texas, aka Stericyle Austin Autoclave (RN102942885 & TCEQ Municipal Solid Waste Type 5 Permit No. 2260A). I informed Mr. Barr that the purpose of the investigation was to review records related to the medical waste generated at Whole Woman's Health of Austin. I requested that Mr. Barr provide three years of medical waste manifests for medical waste generated at Whole Woman's Health of Austin. The investigation was scheduled for May 5, 2011, at 1000.

BACKGROUND

On January 24, 2008, Field Investigator Kathy Roecker and I conducted a Compliance Evaluation Investigation (CEI) at the Stericycle Austin Autoclave. During the investigation a violation for the failure to properly label medical waste transport units was alleged. Compliance documentation was submitted on February 12, 2008. The compliance documentation appeared to properly address the violation; therefore, the violation was resolved.

During the January 24, 2008 CEI, an Additional Issue was also noted. During the investigation it appeared that there was a possibility of an unauthorized discharge during truck/trailer washing activities. Since we did not observe an actual discharge, the concern was addressed as an Additional Issue.

On April 14, 2011, a complaint investigation was conducted at Whole Woman's Health of Austin. During the complaint investigation it was determined that medical waste containing aborted fetuses generated at Whole Woman's Health of Austin were being transported by Stericycle Inc. to the Stericycle Austin Autoclave for treatment. Due to the investigation findings at Whole Woman's Health of Austin it was determined that an investigation would be conducted at the Stericycle Austin Autoclave.

GENERAL FACILITY INFORMATION

Stericycle Austin Autoclave accepts and treats medical and Animal and Plant Health Inspection Services (APHIS) waste including animal waste, bulk blood and blood products, products that have come into contact with body fluids or blood and microbiological wastes. The facility accepts for transfer, but does not treat, non-hazardous pharmaceutical waste, trace amounts of chemotherapeutic waste and pathological wastes consisting of gross human body parts and organs (non-autoclavable waste).

The facility is permitted for 24 hour operations, seven days a week. The maximum amount of waste to be received daily at the facility is 64.2 tons, averaged annually. The maximum amount of waste to be received annually is 23,433 tons. The facility is permitted to operate two autoclaves.

ADDITIONAL INFORMATION

On May 5, 2011, I arrived at the Stericycle Austin Autoclave at approximately 0945 to conduct an onsite investigation. Representing Stericycle Inc. were: Mr. Barr; Mr. Mark Triplett, Environmental Manager; and Mr. John Earnhardt, Regional Operations Manager. I then conducted an entrance interview explaining the purpose and format of the investigation. I informed the representatives that an investigation was conducted at Whole Woman's Health of Austin regarding disposal of medical waste. I informed the representatives that during the investigation it was determined that fetuses resulting from abortions at Whole Woman's Health of Austin were being placed into medical waste boxes along with other medical waste. According to the manifests reviewed during the investigation, it was deteremined that the boxes of medical waste were then transported by Stericycle Inc. to the Stericycle Austin Autoclave for treatment.

The investigation began with a file review. During the file review we reviewed manifests, landfill disposal tickets, the facility's Site Operating Plan (SOP), and Stericycle's Regulated Medical Waste Acceptance Policy. Mr. Barr provided me with three years of medical waste manifests for the medical waste generated at Whole Woman's Health of Austin. The manifests for the medical waste generated at Whole Woman's Health of Austin indicated that all shipments (weekly) were being treated at the Stericycle Austin Autoclave. Therefore, it appears that the Stericycle Austin Autoclave is treating medical waste that contains fetuses. According to the Stericycle Inc.

representatives, after treatment the waste is comingled with other treated medical waste in an open-top container and sent for disposal at the BFI Sunset Farms Municipal Solid Waste (MSW) Landfill (TCEQ MSW Permit No. 1447). According the facility representatives and landfill disposal tickets, prior to April 2010 the treated medical waste from Stericycle Austin Autoclave was disposed of at Texas Disposal Systems MSW Landfill (TCEQ MSW Permit No. 2123).

Stericycle Austin Autoclave's SOP states Stericycle Austin Autoclave accepts and treats Medical and APHIS waste including animal waste, bulk blood and blood products, products that have come into contact with body fluids or blood, microbiological waste and sharps. The facility accepts for transfer but does not treat non-hazardous pharmaceutical waste, trace amounts of chemotherapeutic waste and pathological waste consisting of gross human body parts and organs. According to the 25 TAC 1.132(40)(B)(ii) definition of pathological waste, fetuses and tissue are considered pathological waste. Therefore, Stericycle Austin Autoclave's SOP prohibits the treatment of fetuses (pathological waste). During the investigation it was determined that Whole Woman's Health of Austin's medical waste, which contained fetuses, was being treated at the Stericycle Austin Autoclave.

According to 30 TAC 305.125(1), "The permittee has a duty to comply with all permit conditions. Failure to comply with any permit condition is a violation of the permit and statutes under which it was issued and is grounds for enforcement action, for permit amendment, revocation or suspension, or for denial of a permit renewal application or an application for a permit for another facility." Since Stericycle Austin Autoclave was treating medical waste that contained fetuses, it appears that Stericycle Austin Autoclave did not comply with all of their permit conditions. Therefore, a violation of 30 TAC 305.125(1) has been alleged.

During the investigation it was determined that the medical waste, including fetuses, generated by Whole Woman's Health of Austin was treated by steam disinfection and then sent for disposal in an MSW Type I Landfill. According to 30 TAC 330.1219(b)(3), "Treated recognizable human body parts, tissues, fetuses, organs, and the products of human abortions, spontaneous or induced, shall not be disposed of in a municipal solid waste landfill. These items shall be disposed of in accordance with the provisions of 25 TAC 1.136(a)(4)."

Title 25 TAC 1.136(a)(4)(ii) lists steam disinfection as an approved treatment method if followed by interment. Title 25 TAC 1.132(31) defines interment as, "The disposition of pathological waste by cremation, entombment, burial, or placement in a niche." Since the fetuses generated by Whole Woman's Health of Austin are being treated using steam disinfection followed by disposition in an MSW landfill, it appears that they are not being disposed of in accordance with 25 TAC 1.136(a)(4) as stated in 30 TAC 330.1219(b)(3). Therefore, a violation of 30 TAC 330.1219(b)(3) has been alleged for the improper disposal of fetuses treated by steam disinfection.

After the file review was completed we toured the facility. I observed boxes of medical waste that were labeled for incineration only. I then observed a refrigerated trailer used to store the medical waste prior to shipment to the facility's incinerator in Apopka, Florida.

On June 17, 2011, a copy of a completed TCEQ Exit Interview Form was emailed to Mr. Barr. Mr. Barr confirmed receipt of the TCEQ Exit Interview Form via email.

CONCLUSION

During the investigation it was determined that all medical waste (including fetuses) from Whole Woman's Health of Austin was being sent for steam disinfection at the Stericycle Austin Autoclave. According to Stericycle Austin Autoclave's SOP pathological waste (fetuses) should not be accepted for treatment at the facility. Therefore, a violation of 30 TAC 305.125(1) has been alleged.

During the investigation it was determined that fetuses from Whole Woman's Health of Austin were treated by steam disinfection, followed by disposition in an MSW Type I Landfill. According to 30 TAC 330.1219(b)(3), "Treated recognizable human body parts, tissues, fetuses, organs, and the products of human abortions, spontaneous or induced, shall not be disposed of in a municipal solid waste landfill. These items shall be disposed of in accordance with the provisions of 25 TAC

Page 4 of 5

§1.136(a)(4)." Title 25 TAC 1.136(a)(4)(ii) states that steam disinfection of fetuses is as an approved treatment method if followed by interment. Since the fetuses were being sent for disposal in an MSW Type 1 Landfill, a violation of 30 TAC 330.1219(b)(3) has been alleged.

Due to the apparent seriousness of the alleged violations, a formal enforcement action has been initiated. A Notice of Enforcement letter will be sent via United States Postal Service Certified Mail to Stericycle Inc.

NOE Date: 6/30/2011

OUTSTANDING ALLEGED VIOLATION(S) ASSOCIATED TO A NOTICE OF ENFORCEMENT

Track No: 439039

Compliance Due Date: To Be Determined

Violation Start Date: Unknown

30 TAC Chapter 330.1219(b)(3)

Alleged Violation:

Investigation: 915746

Comment Date: 06/28/2011

Failure to prevent the disposal of treated fetuses at a Municipal Solid Waste (MSW) landfill.

During the investigation it was determined that medical waste containing fetuses from Whole Woman's Health of Austin were being treated by steam disinfection at the Stericycle Austin Autoclave. The treated waste was then sent for disposal at an MSW landfill.

According to 30 TAC 330.1219(b)(3), "Treated recognizable human body parts, tissues, fetuses, organs, and the products of human abortions, spontaneous or induced, shall not be disposed of in a municipal solid waste landfill. These items shall be disposed of in accordance with the provisions of 25 TAC §1.136(a)(4)." Title 25 TAC 1.136(a)(4)(ii) states that steam disinfection of fetuses is an approved treatment method if followed by interment. Since the treated fetuses were being sent for disposal in an MSW Type 1 Landfill, a violation of 30 TAC 330.1219(b)(3) has been alleged.

Recommended Corrective Action: Corrective action will be determined by the TCEQ

Enforcement Division.

Track No: 439047

Compliance Due Date: To Be Determined

Violation Start Date: Unknown

30 TAC Chapter 305.125(1)

Alleged Violation:

Investigation: 915746

Comment Date: 06/28/2011

Failure to comply with all permit conditions.

Stericycle Austin Autoclave's Site Operating Plan (SOP) states Stericycle Austin Autoclave accepts and treats Medical and APHIS waste including animal waste, bulk blood and blood products, products that have come into contact with body fluids or blood, microbiological waste and sharps. The facility accepts for transfer but does not treat non-hazardous pharmaceutical waste, trace amounts of chemotherapeutic waste and pathological waste consisting of gross human body parts and organs. According to the 25 TAC 1.132(40)(B)(ii) definition of pathological waste, fetuses and tissue are considered pathological waste. Therefore, Stericycle Austin Autoclave's SOP prohibits the treatment of fetuses (pathological waste). During the investigation it was determined that Whole Woman's Health of Austin's medical waste, which contained fetuses, was being treated at the Stericycle Austin Autoclave.

According to 30 TAC 305.125(1), "The permittee has a duty to comply with all permit conditions. Failure to comply with any permit condition is a violation of the permit and statutes under which it was issued and is grounds for enforcement action, for permit amendment, revocation or suspension, or for denial of a permit renewal application or an application for a permit for another facility." Since Stericycle Austin Autoclave was treating medical waste that contained fetuses, it appears that Stericycle Austin Autoclave did not comply with all of their permit conditions. Therefore, a violation of 30 TAC 305.125(1) has been alleged.

Recommended Corrective Action: Corrective action will be determined by the TCEQ Enforcement Division.

| Signed Environmental Investigator | Date 6/2 8/// |
|---|----------------------------------|
| SignedSupervisor | Date |
| Attachments: (in order of final report submittal) | |
| Enforcement Action Request (EAR) | Maps, Plans, Sketches |
| Letter to Facility (specify type) : <u>NOE</u> | Photographs |
| Investigation Report | Correspondence from the facility |
| Sample Analysis Results | Other (specify) : |
| ✓Manifests | TCEQE Wit Interview |
| NOR | , |
| | |

Bryan W. Shaw, Ph.D., Chairman
Buddy Garcia, Commissioner
Carlos Rubinstein, Commissioner
Mark R. Vickery, P.G., Executive Director





TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

June 30, 2011

CERTIFIED MAIL 91 7108 2133 3935 2006 4410 RETURN RECEIPT REQUESTED

Mr. Joel Barr, Facility Manager Stericycle Inc. 2607 Hwy. 21 W. Dale, Texas 78616

Re:

Notice of Enforcement for Compliance Evaluation Investigation at:

Stercicycle aka Stericycle Austin Autoclave, 2607 Hwy. 21 W., Dale, Bastrop County Regulated Entity No.: RN102942885 TCEQ ID No.: MSW Permit No. 2260A

Dear Mr. Barr:

On May 5, 2011, Christopher Wiatrek of the Texas Commission on Environmental Quality (TCEQ) Austin Region Office conducted an investigation of the above-referenced regulated entity to evaluate compliance with applicable requirements for municipal solid waste. During this investigation, certain outstanding alleged violations were documented. Enclosed is a summary which lists the investigation findings.

In the listing of the alleged violations, we have cited applicable requirements, including TCEQ rules. Please note that both the rules themselves and the agency brochure entitled *Obtaining TCEQ Rules* (GI 032) are located on our agency website at http://www.tceq.state.tx.us for your reference. If you would like a hard copy of this brochure mailed to you, you may call and request one from either the Austin Region Office at (512)339-2929 or the Central Office Publications Ordering Team at 512-239-0028.

One or more of the violations documented during the subject investigation includes unauthorized activity and you are hereby advised that continued operation is not authorized.

Also, please be advised that the Legislature has granted enforcement powers to the TCEQ to carry out its mission to protect human health and the environment. Due to the apparent seriousness of the alleged violations, formal enforcement action has been initiated, and additional violations may be cited upon further review. We encourage you to immediately begin taking actions to address the outstanding alleged violations.

In responding with prompt corrective action, the administrative penalty to be assessed may be limited.

Mr. Joel Barr June 30, 2011 Page 2

The Commission recognizes that the great majority of the regulated community wants to prevent pollution and to comply with environmental laws. We dedicate considerable resources toward making voluntary compliance achievable. But where compliance has not been met it is our duty to protect the public and the environment by enforcing the state's environmental laws, regulations, and permits.

Also, if you believe the violations documented in this notice have been cited in error, **and** you have additional information that we are unaware of, you may request a meeting to discuss this enforcement matter. To request a meeting, send a letter describing the additional information to the address shown below.

Manager, Waste Section Enforcement Division, MC 219 Re: Enforcement Meeting Request Texas Commission on Environmental Quality P.O. Box 13087 Austin, Texas 78711-3087

If you or members of your staff have any questions, please feel free to contact Christopher Wiatrek in the Austin Region Office at (512)339-2929.

Sincerely,

Barry Kalda, P.G.

Air/Waste Section Manager

Austin Region Office

BJK/cpw

cc: Mark Triplett, Stericycle Environmental Manager

Enclosures: Summary of Investigation Findings

Summary of Investigation Findings

STERICYCLE

Investigation # 915746

2607 HIGHWAY 21 W

Investigation Date: 05/05/2011

DALE, BASTROP COUNTY, TX 78616

Additional ID(s): 2260A

2260

OUTSTANDING ALLEGED VIOLATION(S) ASSOCIATED TO A NOTICE OF ENFORCEMENT

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Alleged Violation:

Investigation: 915746

Comment Date: 6/28/2011

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Recommended Corrective Action: Corrective action will be determined by the TCEQ Enforcement Division.

Track No: 439047

Compliance Due Date: To Be Determined

30 TAC Chapter 305.125(1)

Alleged Violation:

Investigation: 915746

Comment Date: 6/28/2011

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revocation or suspension, a for denial of a permit renewal application can application for a permit for another facility." Since Stericycle Austin Autoclave was treating medical waste that contained fetuses, it appears that Stericycle Austin Autoclave did not comply with all of their permit conditions. Therefore, a violation of 30 TAC 305.125(1) has been alleged.

Recommended Corrective Action: Corrective action will be determined by the TCEQ Enforcement Division.