Texas Commission on Environmental Q Investigation Report



Whole Woman's Health of Austin, LLC CN603853805

WHOLE WOMANS HEALTH OF AUSTIN

RN106143704

Investigation #912801

Incident # 152682

Investigator:

CHRISTOPHER WIATREK

Site Classification

Conducted:

04/14/2011 -- 04/28/2011

No Industry Code Assigned

Program(s):

MEDICAL WASTE

Investigation Type: Compliance Investigation

Location: 8401 N IH 35 STE NO 200

Additional ID(s):

Address: 8401 N IH 35 STE 200;

Activity Type:

REGION 11 - AUSTIN

AUSTIN, TX 78753

MSWCMPL - Investigation of MSW complaint

MEDWASTE - GENERATION

Principal(s):

Role

Name

Title

RESPONDENT

WHOLE WOMANS HEALTH OF AUSTIN LLC

Contact(s):

Role

Name

Phone

MS AMY HAGSTROM-MILLER Work.

(512) 835-5858

Participated in Investigation

Regulated Entity Contact

VICE PRESIDENT

MS TERRY MERRITI

Work

(512) 250-1006

Participated in Investigation

EXECUTIVE

MS AMY MULLINS

Work

(512) 835-8858

Other Staff Member(s):

Role

Name

ASSISTANT

Investigator QA Reviewer Supervisor

KATHY ROECKER KATHY ROECKER BARRY KALDA

Associated Check List

Checklist Name

Unit Name

MSW COMPLAINT INVESTIGATION

WWHA

Investigation Comments:

INTRODUCTION

On March 28, 2011, a written complaint was received at the Texas Commission on Environmental Quality (TCEQ) Austin Region Office alleging unauthorized disposal of medical waste. According to the complainants, Whole Woman's Health of Austin is not properly disposing of the medical waste generated at their facility. Included with the complaint letter were photographs and two signed/notarized TCEQ Citizen Collected Evidence (CCE) affidavits.

The letter submitted indicated that the complainants removed eight large trash bags of waste from

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the dumpster utilized by Whole Woman's Health of Austin. The complainants then went through the bags. The letter submitted by the complainants listed items found in the bags of trash. Photographs of the items listed were included in the CCE.

BACKGROUND

According to the TCEQ Consolidated Compliance and Enforcement Data System, no previous investigations have been conducted at Whole Woman's Health of Austin.

A complaint against Whole Woman's Health of McAllen, LLC has been submitted to the TCEQ Harlingen Region Office regarding similar issues listed in this complaint. The TCEQ Austin Region Office has coordinated with the TCEQ Harlingen Region Office since the waste generated at Whole Woman's Health of McAllen, LLC is being transported to Stericycle Inc's autoclave aka Stericycle Austin Autoclave (RN102942885 & TCEQ MSW Type 5 Permit No. 2260A) located in Daie, Texas (TCEQ Austin Region).

GENERAL FACILITY INFORMATION

According to the Secretary of State Whole Woman's Health of Austin is a Limited Liability Company (LLC). Whole Woman's Health of Austin is located at 8401 N. IH 35 Suite No. 200, Austin, Texas 78753. According to the Travis County Central Appraisal District the property is owned by Abraham & Fedua Yuja.

Whole Woman's Health of Austin is a women's healthcare practice. Whole Woman's Health of Austin offers the following services and procedures:

- " Abortion care
- " Annual exams and pap smears
- " Birth control
- " Treatment for sexually transmitted infections

ADDITIONAL INFORMATION

On April 14, 2011, Field Investigator Kathy Roecker and I conducted an onsite complaint investigation at Whole Woman's Health of Austin. We arrived at the facility at approximately 0910 and met with Ms. Terry Merritt, Vice President. I informed Ms. Merritt of the complaint and our intent to conduct an onsite complaint investigation.

Kathy Roecker and I then reviewed the medical waste manifests that were maintained at the facility. According the manifests reviewed during the investigation, the medical waste generated at the facility is transported by Stericycle (TCEQ Municipal Solid Waste (MSW) Transporter Registration No. 50002) to Stericycle's Austin Autoclave. The manifest indicated that the medical waste is then treated at the Stericycle Austin Autoclave.

During the investigation, Ms. Merritt informed us that Ms. Sue Langham, Texas Department of State Health Services, had contacted her regarding the disposal of medical records. Ms. Merritt then informed us that as a result of the complaint Whole Woman's Health of Austin has hired a document shredding company to shred medical documents and that a lock has been placed on the dumpster used by Whole Woman's Health of Austin.

We then toured the lab area where the medical waste is stored prior to shipment. It was explained that medical waste is placed in red biohazard bags, then placed into boxes provided by Stericycle. Each fetus resulting from an abortion is placed into a hard plastic container and then into a red biohazard bag. The bag is then placed into a freezer where it is stored. When Stericycle arrives to transport the medical waste the individual fetuses are removed from the freezer and placed into another large red biohazard bag. The red biohazard bag containing the fetuses is placed into the medical waste box along with other medical waste generated at the facility that requires treatment. According to the facility representatives and the medical waste manifest reviewed it appears that Stericycle picks up the waste once per week.

During the investigation we observed collection containers for pharmaceutical waste. Ms. Merritt

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informed us that the pharmaceutical waste generated at the facility is transported and disposed of by Stericycle.

Kathy Roecker and I then proceeded to the facility's dumpster. The dumpster was unlocked by an employee of Whole Woman's Health of Austin. The dumpster was empty due to recent waste pick up. The dumpster was located near Fenelon Drive on the Whole Woman's Health of Austin property. We then concluded the onsite investigation.

On April 14, 2011, I contacted Mr. Joel Barr, Stericycle Austin Autoclave Facility Manager, to inquire about treatment and disposal methods for fetuses. Mr. Barr informed me that medical waste containing fetuses or tissue should be sent for incineration. Mr. Barr informed me that according to Stericyle's company policy and operating procedures, it is the generator's responsibility to properly label boxes for incineration. I then informed Mr. Barr that after the review of manifest provided by Whole Woman's Health of Austin, it appeared that medical waste containing fetuses was being treated at the Stericycle Austin Autoclave. I informed him that a separate investigation would be conducted at the Stericycle Austin Autoclave.

On April 18, 2011, I contacted Amy Mullins, Whole Woman's Health of Austin Executive Assistant, to inquire about the labeling of boxes of medical waste containing fetuses. Ms. Mullins informed me that no additional labeling is added to boxes prior to Stericycle. transporting them to the Stericycle Austin Autoclave.

On April 29, 2011, Ms. Mullins emailed me copies of medical waste manifest. The date range of the manifest was from March 5, 2010 through January 12, 2011. The manifest indicated that the medical waste generated at Whole Woman's Health of Austin, including fetuses, is being sent to the Stericycle Austin Autoclave for treatment.

On May 5, 2011, I conducted an onsite investigation at the Stericycle Austin Autoclave. Representing Stericycle during the investigation were: Mr. Barr; Mr. John Earnhardt, Regional Operations Manager; and Mr. Mark Triplett, Environmental Manager. During the investigation we discussed the handling and treatment of fetuses and tissue. The facility representatives indicated that the facility uses steam disinfection to treat medical waste prior to disposal. Title 25 TAC 1.132(45) defines steam disinfection as the act of subjecting waste to steam under pressure under those conditions which effect disinfection. This was previously called steam sterilization. The facility representatives informed me that boxes of waste containing fetuses and/or tissue should be sent for incineration at the Stericycle incinerator in Apopka, Florida. The facility representatives provided me with a copy of their Regulated Medical Waste Acceptance Policy, which they provide to their customers. The facility representatives informed me that Stericycle's company policy requires medical waste generators to label boxes containing non-autoclavable medical waste with "Incinerate Only" labels. Mr. Barr provided me with three years of Whole Woman's Health of Austin's manifests and landfill disposal tickets for treated medical waste. Stericycle Austin Autoclave is currently taking their treated medical waste to BFI Sunset Farms Landfill (MSW Permit No. 1447A) for disposal. Previously, the treated medical waste was taken to Texas Disposal Systems Landfill (MSW Permit No. 2123).

Stericycle Austin Autoclave's Site Operating Plan (SOP) states Stericycle Austin Autoclave accepts and treats Medical and Animal & Plant Health Inspection Service (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, according to the facilities SOP the fetuses from Whole Woman's Health of Austin should not be accepted for treatment at Stericycle Austin Autoclave. For additional information related to the Stericycle Austin Autoclave, see Investigation No. 915746.

On May 17, 2011, I contacted Ms. Mullins and informed her that violations would be alleged as a

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result of the complaint investigation at Whole Woman's Health of Austin. I informed her that a completed copy of the TCEQ Exit Interview Form would be emailed to Ms. Amy Hagstrom-Miller, Whole Woman's Health of Austin Chief Executive Officer (CEO).

On May 19, 2011, I contacted Ms. Susan Langham, Department of State Health Services. Ms. Langham informed me that on May 18, 2011, she conducted an onsite survey at Whole Woman's Health of Austin. Ms. Langham informed me that she removed bags of trash from the dumpster at Whole Woman's Health of Austin. She then reviewed the contents of the bags and no medical waste was observed.

During the investigation it was determined that all medical waste (including fetuses) generated at the Whole Woman's Health of Austin is being transported by Stericycle to the Stericycle Austin Autoclave for treatment. After treatment using steam disinfection, the waste is then disposed of in Type I 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) lists steam disinfection as an approved treatment method for fetuses 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 a 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. In addition to applicable regulations, Stericycle Austin Autoclave's SOP does not allow the acceptance and treatment of pathological wastes, which by regulatory definition includes fetuses. This issue will be addressed by the investigation conducted at the Stericycle Austin Autoclave.

On May 19, 2011, I contacted Ms. Mullins to inquire about how boxes of medical waste are labeled prior to transportation by Stericycle. Ms. Mullins indicated that prior to my investigation, labels were applied to the boxes of medical waste prior to shipment. The labels used on the medical waste boxes did not state "Incinerate Only", but contained the same generator information as the current labels. Ms. Mullins indicated that the boxes of medical waste are not weighed prior to shipment. Ms. Mullins provided a scanned copy of the labels currently used. The labeling contained: the name and address of the generator; the contents of the container; and a blank to write the date of shipment. It does not appear that the weight of each container is written on the label prior to shipment. According to 30 TAC 330.1207(c)(5), "The generator shall affix to each container a label that contains the name and address of the generator, the weight and contents of the container, and either the date of shipment or an identification number for the shipment." Since the label does not include the container weight, a violation of 30 TAC 330.1207(c)(5) has been alleged.

On May 23, 2011, a completed TCEQ Exit Interview Form was emailed to Ms. Hagstrom-Miller. On May 24, 2011, Ms. Hagstrom-Miller confirmed receipt of the form via email.

On May 24, 2011, I contacted Ms. Hagstrom-Miller via telephone to discuss the violations listed on the TCEQ Exit Interview Form. Ms. Hagstrom-Miller confirmed that boxes of medical waste generated at Whole Woman's Health of Austin are not labeled with the container weight prior to shipment. I informed Ms. Hagstrom-Miller that the violations alleged during the investigation would result in formal enforcement.

Citizen Collected Evidence

The complaint letter submitted indicated that the complainants removed eight large trash bags of waste from the dumpster utilized by Whole Woman's Health of Austin. The complainants then went through the bags. The letter submitted by the complainants listed items found in the bags of trash. Thirty-two photographs of the items listed were included in the CCE along with two signed

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and notarized CCE affidavits. The CCE is being returned to the complainants because it is not being used as evidence of the violations documented pursuant to this investigation.

CONCLUSION

During the investigation it was determined that fetuses resulting from abortions at Whole Woman's Health of Austin were being sent for steam disinfection at the Stericycle Austin Autoclave along with other medical waste generated at the facility. 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 as 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.

During the investigation it was determined that boxes of medical waste generated at Whole Woman's Health of Austin were not labeled with the container weight prior to shipment. According to 30 TAC 330.1207(c)(5), "The generator shall affix to each container a label that contains the name and address of the generator, the weight and contents of the container, and either the date of shipment or an identification number for the shipment." Since the container weight is not labeled on the box prior to shipment, a violation of 30 TAC 330.1207(c)(5) 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 Whole Woman's Health of Austin LLC.

NOE Date: 6/3/2011

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

Track No: 435232

Compliance Due Date: To Be Determined

Violation Start Date: Unknown

30 TAC Chapter 330.1219(b)(3)

Alleged Violation:

Investigation: 912801 Comment Date: 06/03/2011

Failure to prevent the disposal of treated fetuses at a municipal solid waste landfill.

During the investigation it was determined that fetuses resulting from abortions at Whole Woman's Health of Austin were being sent for steam disinfection (treatment) at the Stericycle Austin Autoclave along with other medical waste generated at the facility. 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 as 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.

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Track No: 435235

Compliance Due Date: To Be Determined

Violation Start Date: Unknown

30 TAC Chapter 330.1207(c)(5)

Alleged	Viola	ation:
Invaction	tion'	012801

01 Comment Date: 06/03/2011

Failure to ensure that the labels placed on each medical waste container show the weight of the container.

During the investigation it was determined that boxes of medical waste generated at Whole Woman's Health of Austin were not labeled with the container weight prior to shipment. According to 30 TAC 330.1207(c)(5), "The generator shall affix to each container a label that contains the name and address of the generator, the weight and contents of the container, and either the date of shipment or an identification number for the shipment." Since the container weight is not labeled on the box prior to shipment, a violation of 30 TAC 330.1207(c)(5) has been alleged.

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

a A	
Signed Environmental Investigator	Date 6/3/11
Signed Supervisor	Date 6-3-11
Attachments: (in order of final report submittal)	
✓Enforcement Action Request (EAR)	Maps, Plans, Sketches
Letter to Facility (specify type) : NOE	Photographs
Investigation Report	Correspondence from the facility
Sample Analysis Results	Other (specify) :
Manifests	Exit Interviews
NOR	