RCRA COMPLIANCE EVALUATION INSPECTION REPORT

1) Inspector and Author of Report

Daryl R. Himes
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Enforcement Compliance and Assurance Division
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2) Facility Information

Smith and Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 37322

EPA ID: TND980729255

NAICS Code: 339112 – Surgical and Medical Instrument Manufacturing

3) Primary Contact

Billy Powell
Manager Health, Safety & Environmental

4) Inspection Participants

Billy Powell	Smith and Nephew, Inc. (Smith and Nephew)
Angela Horton	Smith and Nephew
William Kimbro	Smith and Nephew
Jason Simpson	Tennessee Department of Environment and Conservation (TDEC)
Jim Holt	TDEC
Daryl Himes	EPA Region 4
Laura Dahlgren	EPA Region 4

5) Date and Time of Inspection

March 10, 2022 9:30 a.m.

6) Applicable Regulations

RCRA Sections 3005 and 3007; 40 Code of Federal Regulations (C.F.R.) Parts 260 - 266, 268, 270, 273, and 279; Tennessee Hazardous Waste Management Act, Tennessee Code Annotated (T.C.A.) 68 - 212 part 1 & 3 and the Used Oil Collection Act of 1993, T.C.A. 68 - 21; the Tennessee Hazardous Waste Management Regulations, Tennessee Rule Chapter 0400 – 12 - 01.

As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.

7) Purpose of Inspection

This announced compliance evaluation inspection (CEI) was conducted to evaluate the facility's compliance with applicable requirements of RCRA and corresponding Tennessee Department of Environment and Conservation (TDEC) regulations.

8) Facility Description

Smith and Nephew is a developer and manufacturing facility of medical orthopedic devices used for surgical implementation. The facility also manufactures specialty tools and hardware used in the installation of its products. Products made by the facility are made from metals and alloys which include titanium, cobalt, chrome, and stainless steels. Plastics are also used to produce various products manufactured by the facility.

Most of the products manufactured at the facility are machined from raw steel alloy rods, bar stock and flat stock. After machining, products may undergo various chemical finishing, polishing, and cleaning processes based on product specifications.

Automated machining tools at the facility use oil and water-based coolants. These oils and coolants are skimmed from the coolant reservoirs and captured as used oil in one gallon or smaller containers located at various machines. Each of the facility's manufacturing areas also utilize an oil rack station which serves as a source location for coolant and oil products used in machines located in that area. Used oil containers are also located at each of these locations to catch any possible drips occuring during the loading of coolants into facility equipment.

After all machining operations are complete, products are sterilized, packaged, and shipped.

The facility is composed of ten buildings located on six contiguous parcels of property comprised of about 34 acres. The facility has approximately 1350 employees and operates 24 hours per day seven days per week.

On March 1, 2021, the facility submitted its most recent hazardous waste notification as a large quantity generator of D001, D002, D003, D007 and D008 characteristic hazardous waste.

9) Previous Inspection History

On April 9, 2013, TDEC conducted a RCRA inspection at Smith and Nephew. Generator discrepancies were observed during the inspection.

10) Findings

On March 10, 2022, EPA inspectors Daryl Himes and Laura Dahlgren, accompanied by Jason Simpson and Jim Holt Tennessee Department of Environmental Conservation inspectors, arrived at Smith and Nephew at approximately 9:30 a.m. Angela Horton, HSE Specialist II, immediately received the inspectors and was shown their credentials. Angela Horton, and the

inspectors were joined by William Kimbro, the facility's Safety Specialist and Billy Powell, Manager, Health, Safety & Environmental, for the opening conference. The inspectors introduced themselves and explained the purpose of the visit. The inspectors described the anticipated use of cameras during the inspection, and provided a request for records.

The three Facility representatives provided an overview of the facility's history and current operations during the opening conference. The company does not appear to meet the Small Business Regulatory Enforcement Fairness Act's classification of a "small business," which is generally set by the Small Business Administration using the business' SIC/NAICS code and annual receipts or number of employees. Therefore, the EPA inspector did not provide a copy of the agency's information sheet for small businesses, which can be found at https://www.epa.gov/compliance/small-business-resources-information-sheet.

Please note that during the walk-through inspection, containers of hazardous waste were observed within satellite accumulation areas (SAAs). Unless otherwise noted, each container observed within these SAAs was observed to be closed and labeled with the words "Hazardous Waste" and an indication of the hazard contents of the container.

In addition, containers of Universal Waste were observed to be properly labeled, dated, and closed at the time of the inspection, unless noted otherwise.

Also, please note that unless otherwise noted, all containers and tanks managing used oil were labeled with the words "Used Oil."

Building A

The walk-through inspection started in this building where research and development, mechanical testing of materials, specialty manufacturing and 3-D printing operations to make materials from nylon were performed. Below are the various areas of the building inspected.

Building A – A1/105

This area was used as an additives manufacturing lab. Four 5-gallon containers of ignitable and reactive hazardous wastes D001/D003 were observed in this area. The containers were not labeled or marked with an indication of the hazard type of the contents of the containers (Photo 1).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)[40 C.F.R. § 262.15(a)], a generator may accumulate as much as 55 gallons of non-acute hazardous waste in containers at or near the point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or without having interim status, as required by Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Tenn. Comp. R. & Regs. 0400-12-01-.01-.05 [40 C.F.R. § 262.16(b) or §262.17(a)], except as required in Tenn. Comp. R. & Regs. 0400-12-01-.03 (f)(1)(vi & vii) [40 C.F.R. § 262.15(a)(7) and (8)], provided that the generator complies with the satellite accumulation area conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.03 (f) [40 C.F.R. § 262.15(a)] (hereinafter referred to as the "SAA Permit Exemption").

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)],

which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Building A – Polymers Lab A1/104

Polymers are tested for use by the facility in this area. No hazardous wastes were being generated in this area at the time of the inspection.

Building A – SEM Lab A1/106

Scanning Electron Microscopy is performed in this lab which provides failure analysis on parts made by the facility. No hazardous wastes were being generated in this area at the time of the inspection.

Building A – Characterization Lab A1/108

No hazardous wastes were being generated in this area at the time of the inspection.

Building A – Tribology Lab A1/114

The study of friction, wear, lubrication, and the design of bearings; the science of interacting surfaces in relative motion is performed in this area.

One 30-gallon container of an ignitable solvent was observed in this area within a metal flammables cabinet. The container was not labeled or marked with an indication of the hazard type of the contents of the container. In addition, the funnel lid attached to the bung of the container was not closed at the time of the inspection (Photo 2).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption, a generator is required to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste; or when temporary venting of a container is necessary

Building A – Materials Labs A1/112 & 113

Materials testing is performed in these labs. No hazardous wastes were being generated in these areas at the time of the inspection.

Building A – Mechanical Testing Lab A1/115

Mechanical testing of various devices is performed in this lab.

One 5-gallon metal container managing hazardous waste aerosol cans was observed in this area. The container was not labeled and was open at the time of the inspection (Photo 3).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(4)], which is a condition of the SAA Permit Exemption, a generator is required to keep containers of hazardous waste closed at all times during accumulation, except when adding, removing, or consolidating waste; or when temporary venting of a container is necessary. for the proper operation of equipment, or to prevent dangerous situations, such as build-up of extreme pressure.

One 5-gallon plastic container managing universal waste batteries was also observed in this area. The container was labeled with a 6-1-2012 accumulation start date.

In addition, three lead acid universal waste batteries were observed in this area. The batteries were not labeled with any universal waste labeling or accumulation start dates (Photo 3).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(1)(b) [40 C.F.R. § 273.9], a "Small Quantity Handler of Universal Waste" (SQHUW) is a Universal Waste handler who does not accumulate 5,000 kilograms or more of Universal Waste (batteries, pesticides, mercury-containing equipment, or lamps, calculated collectively) at any time.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(e)1 [40 C.F.R. § 273.14(a)], a SQHUW must label or mark each Universal Waste battery or container or tank in which the batteries are contained clearly with one of the following phrases: "Universal Waste - Battery(ies)," or "Waste Battery(ies)," or "Used Battery(ies)."

Pursuant to TENN. COMP. R. & REGS. 0400-12-01-.12(2)(f)(1&3) [40 C.F.R. § 273.15(a) and (c)], a SQHUW may accumulate universal waste no longer than one year and must to be able to demonstrate the length of time that the universal waste has accumulated from the date that it became a waste or was received.

Building A – Plastic Liner Production Area

Plastic parts for various joints are made in this area.

A one-gallon container of universal waste lithium-ion batteries was observed in a container near the oil rack on the south end of Building A (Photo 4).

Building A – Plastics Dock Area

In the area of a loading dock door for this building, one 55-gallon container of hazardous waste aerosol cans was observed within a SAA container. One 55-gallon container of used oil was also observed in this area.

Building A – 3D Printing Area

Three-dimensional printing using titanium and nylon is performed in this area. One 55-gallon container of D001/D003 hazardous waste was observed in the area in which titanium is used to make various parts.

No hazardous waste was observed in the area to make parts from nylon using the 3-D printing method.

Building A – A North Manufacturing

One 55-gallon container of hazardous waste aerosol cans was observed in this area. The container was not labeled or marked with an indication of the hazard type of the contents of the containers (Photo 4).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Building B

The walk-through inspection continued through this building where stainless and titanium screws and other instruments are manufactured.

Building B – Nitric Acid Passivation Process

This area uses a passivation process, a widely used metal finishing process to prevent corrosion. The process uses nitric acid to remove free iron from the surface of the stainless steel. Wastewaters from the process go to the facility's wastewater treatment facility for pH treatment and discharge to the Memphis POTW.

Building B – Chemical Finishing Area

Three small chrome plating tanks are operated in this area. No wastewaters from the plating or rinse tanks are generated in this area as all fresh waters entering the rinse tanks are set up to cascade back into the plating tanks.

One 55-gallon container was observed in a 55-gallon container within a SAA. The container was not marked with a placard indicating the hazard code associated with the waste (Photo 6).

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label

its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Building B – Titanium Annodizing Room

Wastewaters associated with titanium anodizing performed in this room are piped and/or sent by trough to the facility's wastewater treatment system before being discharged to the City of Memphis POTW. The anodization process includes a soap wash, water rinse, nitric acid etching process, rinse and alkaline solution colorization process tanks. Wastewaters from this process go to a facility sump (Photo 7) which discharges to the City of Memphis POTW. No sludges are generated as a result of this process in this sump.

Area B Main Shop Floor

This area contains a majority of the facility's screw and instrument manufacturing equipment.

Excess metal and plastics from the manufacturing processes performed in this area are collected and sent off-site for reclamation purposes.

One five-gallon pail of used oil (Photo 8) was observed in the area of several dyes without a "Used Oil" label.

Pursuant to Tenn. Comp. R. & Regs 0400-12-01-.11(3)(c)3. [40 C.F.R. § 279.22(c)(1)], containers and aboveground tanks used to store used oil at generator facilities must be labeled or marked clearly with the words "Used Oil."

In the area of an oil rack located in the B Main Shop Floor, one 55-gallon container of used oil and one 55-gallon container of hazardous waste aerosol cans were observed.

Area B Metal Turnings and Recycling

Steel and platinum metals to be recycled are managed in this area. No hazardous wastes were observed in this area. One 2,500-gallon tank of used oil (Photo 9) labeled as "Used Oil" was observed within a concrete secondary containment system in this area.

Building B – North Side

Knees and partial knees are manufactured in this area. Mechanical work performed on knee replacement parts occupies most of the space within this building. Water smoothing operations on these parts is also performed in this area. A nitric acid passivation process is also performed in this area. No hazardous wastes were generated in this area at the time of the inspection.

Building H – South Side

Replacement parts for patient's femoral knee are manufactured in this area.

One can of hazardous waste aerosol cans was observed in a SAA. The can was not marked with an indication of the type of hazard associated with the waste (Photo 10)

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(f)(1)(v)(II) [40 C.F.R. § 262.15(a)(5)], which is a condition of the SAA Permit Exemption, a generator is required to mark or label its containers (i) with the words "Hazardous Waste" and (ii) with an indication of the hazards of the contents.

Building F – South Side

Hips and Plates are manufactured in this building. Metal works involving both stainless steel and platinum are performed in this building to make the parts for the hips and plates produced. One small passivation line operates in this building. No hazardous wastes result from this operation.

One 55-gallon container of hazardous waste D001/D003 was observed next to a metal works Rhodal slurry hips processing machine.

In the area of the oil rack for this building, one can of hazardous waste aerosol cans was observed in a SAA.

One 5-gallon container of used oil was also observed in this area.

In addition, a one-gallon and 5-gallon containers of universal waste batteries were observed in this area. The 5-gallon container was marked with a 6/11/19 accumulation start date.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(3)(f)1. & 3. [40 C.F.R. § 273.35(a) and (c)], a SQHUW may accumulate universal waste no longer than one year and must to be able to demonstrate the length of time that the universal waste has accumulated from the date that it became a waste or was received.

Building C

Operations performed within this building are for the support of tools used throughout the facility.

One 55-gallon drum of hazardous waste aerosol cans within a SAA and one 55-gallon container of used oil was observed in this building and an associated "Cold Flow" area.

Building I – 90-Day Hazardous Waste Accumulation Area

This building consisted of a metal building constructed on a concrete pad. Seven 55-gallon containers of hazardous waste were observed in the building. Each was labeled with the words "Hazardous Waste," an indication of the hazard associated of the waste; and an accumulation start date of less than 90-days. Each of the containers were closed.

Seven 5-gallon containers of universal waste batteries were observed to be labeled with appropriate universal waste language and accumulation start dates. Each of these containers were closed.

Fourteen 55-gallon drums and one 275-gallon tote of used oil were also observed in this building.

The building was equipped with spill equipment and fire extinguishers.

Record Review

The following hazardous waste records were reviewed at the time of the inspection:

- Last three years of Hazardous Waste Manifests.
- Last three years of Weekly Inspection Logs.
- Training (record) for one of its hazardous waste personnel.
- Hazardous Waste Contingency Plan.

As a result of this review, it was determined that the weekly inspection logs for the weeks of 12-16, 12-23 and 12-30 of 2020 and 1-11, 5-24 and 7-12 of 2021 were missing.

Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(h)1.(i)(V)I&II [40 C.F.R. § 262.17(a)(1)(v)], which is a condition of the LQG Permit Exemption, a generator is required to, at least weekly, inspect central accumulation areas looking for leaking containers and for deterioration of containers caused by corrosion or other factors and record the findings of the inspections, respectively.

Closing Conference

At the conclusion of the walkthrough inspection and record review, a brief closing conference was conducted with each of the facility participants identified above. During the conference, the areas of concern identified during facility walkthrough were identified and discussed.

11) Signed

DARYL HIMES Digitally signed by DARYL HIMES Date: 2022.04.13 22:16:02 -04'00'

Signature Date

Daryl R. Himes
Environmental Engineer

12) Concurrence

ARACELI CHAVEZ Digitally signed by ARACELI CHAVEZ Date: 2022.04.15 09:07:10 -04'00'

Araceli B. Chavez Date

Chief
RCRA Enforcement Section

ATTACHMENT A

Smith and Nephew, LLC

Memphis, Tennessee

COMPLIANCE EVALUATION INSPECTION

TND980729255
March 10, 2022

Photos taken by Daryl R. Himes
Photos taken with Canon Power Shot Elph 360 HS

Photo 1 - Building A - A1/105

Photo 2 – Tribology Lab A1/114

Photo 3 – Mechanical Testing Lab A1/115

Photo 4 – Universal Waste Batteries in the Plastic Liner Production Area

Photo 5 – Building A – A Manufacturing North

Photo 6 - 55-gallon container in Building B Chemical Finishing Area

Photo 7 - Wastewater sump prior to discharge to POTW

Photo 8 – Five-gallon container of used oil without a label

Photo 9 – Area B Metal Turnings and Recycling Area

Photo 10 – H Building South Side Aerosol Cans Drum