
UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

REGION III

# STATEMENT OF BASIS

Thermo Fisher Scientific

Middletown, VIRGINIA

EPA ID NO. VAD093012417

March 9, 2011

| CONCURRENCES | | | | | | | | |
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| SYMBOL | 3LC20 | 3LC20 | 3LC00 | | | | | |
| SURNAME | Jacobi | Pizarro | Ferdas | | | | | |
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# I. Introduction

## A. Facility Name

The United States Environmental Protection Agency (EPA) has prepared this Statement of Basis (SB) for the Thermo Fisher Scientific facility located at 8365 Valley Pike, Middletown, Virginia (hereinafter referred to as the Facility).

The Facility is subject to the Corrective Action program under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, and the Hazardous and Solid Waste Amendments (HSWA) of 1984, 42 U.S.C. Sections 6901 to 6992k. The Corrective Action program is designed to ensure that certain facilities subject to RCRA have investigated and cleaned up any releases of hazardous waste and hazardous constituents that have occurred at their property.

Information on the Corrective Action program as well as a fact sheet for the Facility can be found by navigating http://www.epa.gov/reg3wcmd/correctiveaction.htm.

## B. Proposed Decision

EPA's review of available information indicates that there are no unaddressed releases of hazardous waste or hazardous constituents from the Facility. Based on that assessment, our proposed decision is that no further investigation or cleanup is required. EPA's proposed decision meets the criteria for "Corrective Action Complete without Controls" set forth in EPA Guidance found in the Federal Register / Vol. 68, No. 37 / Tuesday, February 25, 2003 / Notices [FRL – 7454-7] pages 8757 to 8764.

EPA has determined that its proposed decision for the Facility is protective of human health and the environment and that no further corrective action or controls are necessary at this time.

## C. Public Participation

Interested persons are invited to comment on EPA's proposed decision. The public comment period will last thirty (30) calendar days from the date that notice is published in a local newspaper. Comments may be submitted by mail, fax, e-mail, or phone to Mr. Mike Jacobi at the address listed below. EPA will hold a public meeting to discuss this proposed decision upon request. Requests for a public meeting should be made to Mr. Mike Jacobi at the address listed below.

EPA has developed an Administrative Record (AR) for this proposed decision which contains all information considered by EPA during the process. The AR is available at the following location:

U.S. EPA Region III
1650 Arch Street
Philadelphia, PA 19103
Contact: Mr. Mike Jacobi (3LC20)
Phone: (215) 814-3435
Fax: (215) 814-3114
Email: jacobi.mike@epa.gov

EPA encourages interested persons to participate in the remedy selection process by reviewing this SB and documents contained in the AR. The AR contains the complete information that EPA reviewed prior to this proposed decision.

EPA will address all significant comments received during the public comment period. If EPA determines that new information or public comments warrant a modification to the proposed decision, EPA will modify the proposed decision or select other alternatives based on such new information and/or public comments. EPA will approve its final decision in a document entitled the Final Decision and Response to Comments (FDRTC). Any person who comments on the decision will automatically receive a copy of the FDRTC. Any other person wishing to receive a copy of the FDRTC may obtain one by contacting Mr. Mike Jacobi.

## II. Facility Background

The Thermo Fisher Scientific is located at 8365 Valley Pike in Middletown, Frederick County, Virginia. The Facility is located in a mixed industrial and agricultural area. The property on which the Facility was constructed is 18 acres in size. The Facility is an in-vitro diagnostic manufacturing plant. The plant is approximately 230,000 square feet in size and consists of a single building. The plant is comprised of several light manufacturing and production areas, shipping and receiving area, warehouse, storage areas within a single contiguous building, and associated asphalt parking lots, roadways, and landscaped areas. The majority of the manufacturing plant was constructed in 1978, with several additions added and renovations performed over the years. The largest expansion of the facility occurred in 1987.

The facility formulates aqueous reagents and human and bovine-based calibration products used for clinical diagnostic systems. The products are used by clinical laboratories and hospitals to conduct various biochemical and hematological assays on human blood and urine samples. The products are considered United States Food and Drug Administration (FDA) Class 1, 2 and 3 medical devices and are regulated by the FDA. Manufacturing at the facility began in 1978. Manufacturing activities include mixing of reagents and calibration products, packaging of liquids into smaller aliquots, and lyophilization (freeze drying) of liquids to produce powdered reagents. Approximately 170 employees currently work at the facility which currently operates 24 hours a day, 7 days a week.

Over the years, ownership and the name of the facility has changed via sale and acquisition. The facility is currently owned by Thermo Fisher Scientific. Some of the past owners and operators of the facility include Technicon Instruments, Revlon Health Care Group, Pantry Pride, Cooper-Technicon, Miles Inc., and BAYER. The initial RCRA Part B permit

application for the facility was filed when the facility was owned by Technicon Instruments Corporation. Reagent manufacturing operations were similar and have changed little since manufacturing operations began at the facility.

Various chemicals and petroleum products have historically been and are currently used during the manufacturing process. The raw chemicals and petroleum products are stored in tanks, 55-gallon drums, various capacity containers, and Gaylord-style boxes. The hazardous and non-hazardous wastes generated at the facility are stored in 55-gallon drums, small containers, and boxes pending disposal/treatment. The facility is listed as a Large Quantity Generator of hazardous waste. Other wastes generated at the facility include general trash, recyclable fluorescent lamps, and petroleum-based oils and lubricants. The fluorescent lamps (handled as a Universal waste) are collected in boxes and transported off site for recycling on a periodic basis.

## III. Summary of Environmental History

In 1987, Thermo Fisher excavated and removed a 20,000 gallon fuel oil underground storage tank (UST) located adjacent to the manufacturing building on the southeast side. In 1996, a 1,500 gallon petroleum UST and a 3,000 gallon aboveground storage tank (AST) located in the same area were also removed from service. As part of the tank removals, soil samples were collected and a perched water sample from within the excavation of the 20,000 gallon UST was collected. Soil sample results indicated Total Petroleum Hydrocarbons-Diesel Range Organics (TPH-DRO) concentrations of approximately 120 mg/kg. Results for TPH- DRO concentrations in the perched water within the excavation were approximately 13,000 ug/l. The perched water was removed and the excavation was backfilled with clean fill. Follow up soil sampling from June 2000 indicated TPH-DRO concentrations ranging from 41 – 249 mg/kg. The Virginia Department of Environmental Quality (VDEQ) determined that TPH-DRO was bound vertically and horizontally in the soil and that there had been no impact to groundwater in the immediate area. Upon removal of the 1,500 gallon UST, soil sample results indicated that TPH was not detected above the laboratory detection limit of 10 mg/kg.

In August 2010, the facility conducted confirmatory sampling of soil and groundwater within the area of tanks at the request of VDEQ. Three soil borings were advanced to bedrock refusal (approximately 11-15 feet below ground surface) utilizing direct push technology. Soil at each boring was field screened for hydrocarbons using a photo-ionization detector (PID). PID results did not indicate the presence of petroleum hydrocarbons.

Two soil samples were collected from in-situ soil beneath the former tank pit (13 feet) below ground surface (bgs) and from soil at depth above bedrock (15 feet bgs) and analyzed for VOCs and semi-volatile organic compounds (SVOCs). Constituents detected in soil include carbon disulfide, benzo(a)pyrene, chrysene, dibenz(a,h)anthracene, and fluoranthene. However, soil sample results indicate that the only constituent detected above EPA's Risk Based Concentration (RBC) for residential soil was benzo(a)pyrene (0.048 mg/kg) at 13 feet below ground surface. The depth of this sample was collected from in-situ soil located just below the former tank pit location, which consists of clean backfill material.

Benzo(a)pyrene was detected at a concentration only slightly above its residential RBC (0.015 mg/kg), but below its industrial RBC of 0.21 mg/kg. A second sample was collected from 15 feet below ground surface in the same boring location. Benzo(a)pyrene results (0.0021 mg/kg) were an order of magnitude below the residential RBC (0.015 mg/kg). Additionally, a groundwater sample was collected from an existing monitoring well located approximately 20 feet downgradient of the tanks area and analyzed for VOCs and SVOCs.

Groundwater sample results indicated that 2-methylnaphthalene, bis(2-ethylhexyl)phthalate, pyrene, and naphthalene were detected in groundwater. However, concentrations for the detected constituents were below Maximum Contaminant Levels (MCLs) for drinking water and EPA's RBC for tap water.

In 1996, Thermo Fisher achieved clean closure for soil at three storage container areas located within the facility and a former dry well located on the southeastern portion of the property near the manufacturing building. The three storage areas were used to store hazardous and non-hazardous waste generated during facility operations from the late 1970's to the early 1990's. The dry well was identified during the VDEQ approved RCRA closure activities and subsequently investigated as part of the closure activities. These areas were closed between September 1995 and March 1996. Closure activities included soil sampling associated with the three storage areas and the dry well. Volatile Organic Compounds (VOCs), formaldehyde, and metals were detected in soil samples collected as part of the closure activities. The soil was excavated and addressed to the satisfaction of the VDEQ. Certified Clean Closure for soil at the unit and the dry well was granted by the VDEQ in 1996. VDEQ determined that it was unnecessary to assess groundwater during closure activities based on the findings in soil

From 1998 to 2003, three small releases occurred and have been documented. The releases included a fuel oil spill of less than 25 gallons at a 4,000 gallon AST, an estimated 385 gallon release of formaldehyde within the facility building that was captured by secondary containment, and a release of approximately 1 liter of diesel fuel in the facility's parking lot near the shipping dock. These releases were contained and cleaned up appropriately. No adverse impact to human health or the environment was observed.

Based on the information above, the EPA in conjunction with the VDEQ has determined that past releases and/or impacts to the environment have been appropriately addressed and/or remediated. There is currently no adverse impact to human health and the environment from this facility. The AR includes detailed documents containing the information above. The AR may be reviewed at the address listed in Section I.C and is available upon request.