DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION
Interim Final 2/5/99
RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA725)
Current Human Exposures Under Control

Facility Name: **Thermo Fisher Scientific**
Facility Address: **8365 Valley Pike, Middletown, VA 22645**
Facility EPA ID #: **VAD093012417**

1. Has **all** available relevant/significant information on known and reasonably suspected releases to soil, groundwater, surface water/sediments, and air, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), and Areas of Concern (AOC)), been **considered** in this EI determination?

☒ If yes - check here and continue with #2 below.

☐ If no - re-evaluate existing data, or

☐ If data are not available, skip to #6 and enter "IN" (more information needed) status code.

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EI developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of "Current Human Exposures Under Control" EI

A positive "Current Human Exposures Under Control" EI determination ("YE" status code) indicates that there are no "unacceptable" human exposures to "contamination" (i.e., contaminants in concentrations in excess of appropriate risk-based levels) that can be reasonably expected under current land- and groundwater-use conditions (for all "contamination" subject to RCRA corrective action at or from the identified facility (i.e., site-wide)).

Relationship of EI to Final Remedies

While Final remedies remain the long-term objective of the RCRA Corrective Action program the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, GPRA). The "Current Human Exposures Under Control" EI are for reasonably expected human exposures under current land- and groundwater-use conditions ONLY, and do not consider potential future land- or groundwater-use conditions or ecological receptors. The RCRA Corrective Action program's overall mission to protect human health and the environment requires that Final remedies address these issues (i.e., potential future human exposure scenarios, future land and groundwater uses, and ecological receptors).

Duration / Applicability of EI Determinations

EI Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

BACKGROUND

The Thermo Fisher Scientific (Thermo Fisher) facility 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 invitro 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. 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. Thermo Fisher purchased the facility in 2000 from Bayer Corporation (BAYER). 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 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. Approximately 170 employees currently work at the facility which currently operates 24 hours a day, 7 days a week.

Various hazardous chemicals, non-hazardous 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 and currently holds an air registration permit for air discharges; however, the facility is in the process of canceling the air permit. The air permit is being cancelled because the chemical which required the air permit is no longer handled in this capacity at the facility. Hazardous wastes historically generated, handled, and stored at the facility include the following:

- D001 - waste ignitable liquids (flash point <140 degrees °F)
- D002 – waste nitric and sulfuric acids
- D009 – mercury wastes
- F001 – spent halogenated solvents (trichloroethylene)
- F003 – waste non-halogenated solvents (paint and solvents)
- U123 – waste formic acid
- U002 – waste acetone (ignitable)
- U220 – waste methyl benzene (toluene)
- U211 – waste carbon tetrachloride
- U044 – waste chloroform
- U188 – waste phenol
- U154 – waste methanol (ignitable)
- U122 – waste methylene oxide (formaldehyde)
- U133 – waste hydrazine (reactive)
- U057 – waste cyclohexanone (ignitable)
- U019 – waste benzene (ignitable)
- U117 – waste ethane, 1,1-oxybis (ignitable)
- P012 – waste arsenic (III) oxide
- P092 – waste phenylmercuric acetate
- P105 – waste sodium azide
- P030 – waste cyanide, soluble salts

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. The wastes generated and stored at the facility are mainly attributable to product manufacturing and quality assurance testing.

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2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective risk-based "levels" (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

	Yes	No	?	Rationale / Key Contaminants
Groundwater		X		
Air (indoors)[2]		X		
Surface Soil (e.g., <2 ft)		X		
Surface Water		X		
Sediment		X		
Subsurf. Soil (e.g., >2 ft)		X		
Air (outdoors)		X		

☒ If no (for all media) - skip to #6, and enter "YE," status code after providing or citing appropriate "levels," and referencing sufficient supporting documentation demonstrating that these "levels" are not exceeded.

☐ If yes (for any media) - continue after identifying key contaminants in each "contaminated" medium, citing appropriate "levels" (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

☐ If unknown (for any media) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):

In 1987 Thermo Fisher removed a 20,000 gallon fuel oil UST from the ground. In 1996, a 1,500 gallon petroleum UST and a 3,000 gallon AST were also removed from service. AOC 1 consists of the area at which these tanks were previously located. 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 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 a TPH DRO concentrations ranging from 41 – 249 mg/kg. The 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 1996, Thermo Fisher received clean closure for soil related to SWMU 10. SWMU 10 refers to three closed interim status container areas (SWMU 4, 5, and 6) and a dry well. 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. 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. The facility and the VDEQ determined that it was unnecessary to assess groundwater during closure activities based on the findings in soil.

In August 2010, the facility conducted confirmatory sampling of soil and groundwater within the area of AOC 1 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 bgs) and from soil at depth above bedrock (15 feet bgs) and analyzed for volatile and semi-volatile organic compounds (VOCs and 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 risk-based regional screening levels (RSLs) 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 RSL (0.015 mg/kg), but still at the low end of the EPA-recommended risk range for carcinogens (10^{-4} to 10^{-6}.). 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 RSL (0.015 mg/kg). A groundwater sample was collected from an existing monitoring well located approximately 20 feet downgradient of AOC 1 and analyzed for VOCs and SVOCs. Constituents detected in groundwater includes 2-methylnaphthalene, bis(2-ethylhexyl)phthalate, naphthalene, and pyrene. However, groundwater sample results indicated no detections above drinking water standards or regional screening levels for tap water.

Footnotes:

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based "levels" (for the media, that identify risks within the acceptable risk range).

[2] Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest that unacceptable indoor air concentrations are more common in structures above groundwater with volatile contaminants than previously believed. This is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration necessary to be reasonably certain that indoor air (in structures located above (and adjacent to) groundwater with volatile contaminants) does not present unacceptable risks.

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3. Are there **complete pathways** between "contamination" and human receptors such that exposures can be reasonably expected under the current (land- and groundwater-use) conditions?

Summary Exposure Pathway Evaluation Table

Potential **Human Receptors** (Under Current Conditions)

"Contaminated" Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food[3]
Groundwater							
Air (indoors)							
Soil (surface, e.g., <2 ft)							
Surface Water							
Sediment							
Soil (subsurface e.g., >2 ft)							
Air (outdoors)							

Instructions for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors' spaces for Media which are not "contaminated" as identified in #2 above.

2. enter "yes" or "no" for potential "completeness" under each "Contaminated" Media -- Human Receptor combination (Pathway).

Note: In order to focus the evaluation to the most probable combinations some potential "Contaminated" Media - Human Receptor combinations (Pathways) do not have check spaces ("___"). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

☐ If no (pathways are not complete for any contaminated media-receptor combination) - skip to #6, and enter "YE" status code, after explaining and/or referencing condition(s) in-place, whether natural or man-made, preventing a complete exposure pathway from each contaminated medium (e.g., use optional Pathway Evaluation Work Sheet to analyze major pathways).

☐ If yes (pathways are complete for any "Contaminated" Media - Human Receptor combination) - continue after providing supporting explanation.

☐ If unknown (for any "Contaminated" Media - Human Receptor combination) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):

[3] Indirect Pathway/Receptor (e.g., vegetables, fruits, crops, meat and dairy products, fish, shellfish, etc.)

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4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be **"significant"**[4] (i.e., potentially "unacceptable" because exposures can be reasonably expected to be: 1) greater in magnitude (intensity, frequency and/or duration) than assumed in the derivation of the acceptable "levels" (used to identify the "contamination"); or 2) the combination of exposure magnitude (perhaps even though low) and contaminant concentrations (which may be substantially above the acceptable "levels") could result in greater than acceptable risks)?

☐ If no (exposures can not be reasonably expected to be significant (i.e., potentially "unacceptable") for any complete exposure pathway) - skip to #6 and enter "YE" status code after explaining and/or referencing documentation justifying why the exposures (from each of the complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

☐ If yes (exposures could be reasonably expected to be "significant" (i.e., potentially "unacceptable") for any complete exposure pathway) - continue after providing a description (of each potentially "unacceptable" exposure pathway) and explaining and/or referencing documentation justifying why the exposures (from each of the remaining complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

☐ If unknown (for any complete pathway) - skip to #6 and enter "IN" status code

Rationale and Reference(s):

[4] If there is any question on whether the identified exposures are "significant" (i.e., potentially "unacceptable") consult a human health Risk Assessment specialist with appropriate education, training and experience.

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5. Can the "significant" **exposures** (identified in #4) be shown to be within **acceptable** limits?

☐ If yes (all "significant" exposures have been shown to be within acceptable limits) - continue and enter "YE" after summarizing and referencing documentation justifying why all "significant" exposures to "contamination" are within acceptable limits (e.g., a site-specific Human Health Risk Assessment).

☐ If no - (there are current exposures that can be reasonably expected to be "unacceptable")- continue and enter "NO" status code after providing a description of each potentially "unacceptable" exposure.

☐ If unknown (for any potentially "unacceptable" exposure) - continue and enter "IN" status code.

Rationale and Reference(s):

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6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI (event code CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

☒ YE - Yes, "Current Human Exposures Under Control" has been verified. Based on a review of the information contained in this EI Determination, "Current Human Exposures" are expected to be "Under Control" at the Thermo Fisher facility, EPA ID #VAD093012417, located at 8365 Valley Pike, Middletown, Virginia under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

☐ NO - "Current Human Exposures" are NOT "Under Control."

☐ IN - More information is needed to make a determination.

Completed by (signature) Brett Fisher Date: 1-6-2011
(print) Brett Fisher, P.G.
(title) RCRA CA Project Manager

Supervisor (signature) Jutta Schneider Date 1-7-2011
(print) Jutta Schneider
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(EPA Region or State) VDEQ

Locations where References may be found:

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Virginia Department of Environmental Quality
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