DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION
Interim Final 2/5/99
RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA750)
Migration of Contaminated Groundwater 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 the groundwater media, 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 #8 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 "Migration of Contaminated Groundwater Under Control" EI

A positive "Migration of Contaminated Groundwater Under Control" EI determination ("YE" status code) indicates that the migration of "contaminated" groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original "area of contaminated groundwater" (for all groundwater "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 "Migration of Contaminated Groundwater Under Control" EI pertains ONLY to the physical migration (i.e., further spread) of contaminated ground water and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

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. 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 discontinued 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. Is **groundwater** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective "levels" (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

☐ If yes - continue after identifying key contaminants, citing appropriate "levels," and referencing supporting documentation.

☒ If no - skip to #8 and enter "YE" status code, after citing appropriate "levels," and referencing supporting documentation to demonstrate that groundwater is not "contaminated."

☐ If unknown - skip to #8 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.

From 1998 to 2003, three small releases occurred and have been documented. The releases include a fuel oil spill of less than 25 gallons at AOC 3 (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 do not indicate potential impacts to groundwater.

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 and from soil at depth above bedrock and analyzed for volatile and semi-volatile organic compounds (VOCs and SVOCs). Soil sample results indicated that the only chemical detected above screening criteria was benzo(a)pyrene, which was detected above its residential RSL, but below its SSL DAF-1 and industrial RSL. A groundwater sample was collected from an existing monitoring well located approximately 20 feet downgradient of AOC 1 and analyzed for VOCs and SVOCs. Groundwater sample results indicated that 2-methylnaphthalene, bis(2-ethylhexyl)phthalate, and naphthalene were detected in groundwater below drinking water standards and regional screening levels for tap water.

Based on information provided above and in the RCRA Site Visit Report, the RCRA Closure Report for SWMU 10, and the RCRA CA Site Assessment Report including additional reports and files, it is determined that there is no existing impacts to groundwater or potential for groundwater contamination above appropriately protective levels.

References:

1. RCRA Site Assessment Report by ERM, November 23, 2010
2. RCRA Site Visit Report by Tetra Tech EC, Inc., February 28, 2007
3. RCRA Closure Report for SWMU 10 by ICF Kaiser Engineers, Inc., April 19, 1996
4. UST Closure Files for the 20,000 Gallon UST, 3,000 Gallon AST, and 1,500 Gallon UST (AOC 1), 1987-2000

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 appropriate "levels" (appropriate for the protection of the groundwater resource and its beneficial uses).

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3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within "existing area of contaminated groundwater"[2] as defined by the monitoring locations designated at the time of this determination)?

   ☐ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the "existing area of groundwater contamination"[2]).

   ☐ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the "existing area of groundwater contamination"[2]) – skip to #8 and enter "NO" status code, after providing an explanation.

   ☐ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

[2] "existing area of contaminated groundwater" is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of "contamination" that can and will be sampled/tested in the future to physically verify that all "contaminated" groundwater remains within this area, and that the further migration of "contaminated" groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

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4. Does "contaminated" groundwater **discharge** into **surface water** bodies?

   ☐ If yes - continue after identifying potentially affected surface water bodies.

   ☐ If no - skip to #7 (and enter a "YE" status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater "contamination" does not enter surface water bodies.

   ☐ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

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5. Is the **discharge** of "contaminated" groundwater into surface water likely to be **"insignificant"** (i.e., the maximum concentration[3] of each contaminant discharging into surface water is less than 10 times their appropriate groundwater "level," and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or eco-systems at these concentrations)?

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☐ If yes - skip to #7 (and enter "YE" status code in #8 if #7 = yes), after documenting:
1) the maximum known or reasonably suspected concentration[3] of key contaminants discharged above their groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and
2) provide a statement of professional judgment/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or eco-system.

☐ If no - (the discharge of "contaminated" groundwater into surface water is potentially significant) - continue after documenting:
1) the maximum known or reasonably suspected concentration[3] of each contaminant discharged above its groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and
2) for any contaminants discharging into surface water in concentrations[3] greater than 100 times their appropriate groundwater "levels," the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

☐ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

[3] As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

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6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be "**currently acceptable**" (i.e., not cause impacts to surface water, sediments or eco-systems that should not be allowed to continue until a final remedy decision can be made and implemented[4])?

☐ If yes - continue after either:
1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site's surface water, sediments, and eco-systems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater;
OR
2) providing or referencing an interim-assessment[5], appropriate to the potential for impact that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment "levels," as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

☐ If no - (the discharge of "contaminated" groundwater can not be shown to be "**currently acceptable**") - skip to #8 and enter "NO" status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or eco-systems.

☐ If unknown - skip to 8 and enter "IN" status code.

Rationale and Reference(s):

[4] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

[5] The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

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7. Will groundwater **monitoring** / measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the "existing area of contaminated groundwater?"

☐ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations, which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

☐ If no - enter "NO" status code in #8.

☐ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

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8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), 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, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the Thermo Fisher Scientific facility, EPA ID # VAD093012417, located at 8365 Valley Pike, Middletown, VA 22645. Specifically, this determination indicates that the migration of "contaminated" groundwater is under control, and that monitoring will be conducted to confirm that contaminated groundwater remains within the "existing area of contaminated groundwater" This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

☐ NO - Unacceptable migration of contaminated groundwater is observed or expected.

☐ 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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Locations where References may be found:

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