DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action
Environmental Indicator (EI) RCRA Info code (CA750)
Migration of Contaminated Groundwater Under Control

Facility Name: **Wyeth (Pfizer) Pharmaceutical – Rouses Point**
Facility Address: **64 Maple Street**
Facility EPA ID #: **NYD002081396**

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 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 "contaminated" 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 RCRAInfo national database ONLY as long as they remain true (i.e., RCRAInfo status codes must be changed when the regulatory authorities become aware of contrary information).

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?

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

   _____ If no - re-evaluate existing data, or

   _____ If data is not available, skip to #8 and enter "IN" (more information needed) status code.

BACKGROUND

Location: The site is located at the intersection of Maple Street (east of the site) and Academy Street (south of the site) in the Village of Rouses Point, NY. Railroad tracks border the property along the west side. The site is approximately 800 feet west of the northern end of Lake Champlain and 3,300 feet south of the Canadian Border. The site includes land within the Village of Rouses Point and the Town of Champlain. The properties are currently owned and operated by Pfizer (formerly Wyeth Pharmaceuticals) as a pharmaceutical manufacturing facility.

Site Features: The site had contained two operational facilities; the Main Plant and the Chemical Development Plant. The Main Plant, located primarily on the eastern portion of the site, includes approximately 1 million square feet of manufacturing and supporting infrastructure space. There are manufacturing buildings, warehouse space, a boiler house, and air treatment buildings located here. The Main Plant portion of the site maintains an address of 64 Maple Street. Operations at the Main Plant include, or have included, the manufacturing, primary processing and packaging of over the counter and prescription pharmaceuticals.

The Chemical Development Plant, was located on the western portion of the site contains approximately 120,000 square feet of pharmaceutical research and development space and warehouse space. The process wastewater treatment plant, steam stripper, tank farm, fire water system, various storage buildings, a tank farm and the greater than 90 day hazardous waste storage facility were located here. The Chemical Development Plant had an address of 100 Academy Street. The Chemical Development Plant was demolished between September 2014 and May 2015. No structures remain.

Topographically, the site is generally flat, sloping gently to the east from the rail road tracks to Maple Ave.

Current Zoning: The site is zoned I-2, Industrial

Operable Units: The site maintains a Part 373 Corrective Action Permit.

Site Geology and Hydrogeology: No water supply wells were identified within one mile of the site. There is public water in the Village of Rouses Point, the source of which is Lake Champlain. Site hydrogeologic conditions have been evaluated in detail through the installation and monitoring of 66 overburden groundwater monitoring wells and through the completion of a groundwater flow model with particle tracking.

Groundwater can be found in limited quantities in the lower of two glacial till layers. There is an upper till unit consisting of medium dense to dense soils with low permeability which does not yield significant groundwater. The lower till unit appears to be the more significant water bearing unit and the primary unit through which groundwater flows. The upper till unit is likely representative of vadose zone-type conditions and the lower unit is more likely representative of the regional groundwater flow conditions. Based on the observations made during drilling of the bedrock, the bedrock at the site is solid, competent and does not readily transmit water. The bedrock is mapped as the Stony Point Shale, a black, fissile, carbonaceous, calcareous shale. The depth to bedrock ranges from 18 feet in the northeast to 35 feet in the southwest.

Recharge to the groundwater flow system is likely to originate primarily in unpaved portions of the area upgradient of the facility and in some of the drainage swales on and around the facility. Groundwater discharges to the Richelieu River/Lake Champlain. There are several closed contour drainage swales on the Site which likely serve as areas of enhanced recharge to the flow system during wet times of the year.

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?

   X 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 known or reasonably suspected to be "contaminated."

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

Rationale:

Contaminants of Concern (COC) were identified in groundwater at the Site and off-site to the east-southeast. These were primarily carbon tetrachloride, trichloroethene, 1,2-dichloroethane, and cis-1,2-dichloroethene. It appears that these COCs are a result of historic use and releases from the manufacturing operations at the Site and do not appear to represent a current or ongoing source or sources of a release. The exact release mechanisms and locations have not been identified to date; however, it is suspected that leaks in former sewer systems in historic solvent use areas and/or management/disposal practices resulted in the historic releases.

The COCs exist in on-site and off-site groundwater monitoring wells screened in the upper till and lower

[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).

till units, with higher overall constituent concentrations found in the lower till. NYSDEC groundwater quality standards are exceeded primarily in the area extending off-site to the east-southeast of the facility, with the highest concentrations generally detected at the intersection of Maple Street/Academy Street in between MW-37 and MW-21 in the lower till. The COCs appear to collect at this location in the lower till confined by a bedrock feature which retards migration to the east.

References:

Woodard & Curran. March 29, 2013. Draft Corrective Measures Study Report, Pfizer, Rouses Point, NY.

Woodard & Curran. September 17, 2015. 2014-2015 Annual Progress Report, Pfizer, Rouses Point, NY.

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

    X 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:

The highest concentrations of COCs in the groundwater have been consistently detected at the intersection of Maple and Academy Streets in the lower till confined by a bedrock feature which retards migration to the east. This intersection has been the focus of additional groundwater investigations and monitoring as part of the design and implementation of an In-situ Chemical Oxidation (ISCO) program. This area is referred to as the Primary Treatment Area for the ISCO Interim Corrective Measure (ICM). Groundwater monitoring results downgradient of this area have remained consistent and have demonstrated a stable/shrinking plume.

[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.

Based on the results of 2015 and 2016 progress groundwater monitoring activities in the Primary Treatment Area, a continuation of the ISCO ICM program is proposed to be conducted using Modified Fenton's Reagent and Activated Sodium Persulfate to further reduce COCs in groundwater in this area. The Primary Treatment Area is located off-site in the intersection of Maple/Academy Street and measures approximately 1,950 square feet. The material to be injected is the same as that which was demonstrated to be effective in reducing COCs in groundwater during the 2013 ISCO ICM. The Primary Treatment Area ISCO injection/monitoring well network consists of nine (9) injection points and three (3) monitoring points.

References:

Woodard & Curran. March 29, 2013. Draft Corrective Measures Study Report, Pfizer, Rouses Point, NY.

Woodard & Curran. September 17, 2015. 2014-2015 Annual Progress Report, Pfizer, Rouses Point, NY.

Woodard & Curran. June 10, 2016. Request to Reauthorize the 2014 In-Situ Chemical Oxidation (ISCO) Interim Corrective Measure (ICM) Work Plan for Pfizer, Rouses Point, NY.

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

__**X**__ 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 "contaminated" does not enter surface water bodies.

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

Rationale:

Lake Champlain is the potentially affected surface water body.

References:

Woodard & Curran. March 29, 2013. Draft Corrective Measures Study Report, Pfizer, Rouses Point, NY.

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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__X__ 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 judgement/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:

Although there is a potential for contaminated groundwater to discharge to Lake Champlain, discharge to the Lake has not been documented. In addition, samples from monitoring wells at the perimeter of the monitoring well network have contained low levels of COCs, which are less than 10 times their groundwater standard.

It should also be noted that the concentrations of COCs detected in the most downgradient wells were evaluated as part of a Screening Level Ecological Risk Assessment (SLERA, included as Appendix G of the Draft Corrective Measures Study Report, dated March 29, 2013). The SLERA concluded that the concentrations of COCs detected in the downgradient wells are not expected to present a potential for adverse effects to the aquatic resources of Lake Champlain.

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

References:

Woodard & Curran. March 29, 2013. Draft Corrective Measures Study Report, Pfizer, Rouses Point, NY.

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.

[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.

Rationale:

References:

Type here

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 Aexisting area of contaminated groundwater?

   X 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:

As recommended in the Draft Corrective Measures Study Report, dated March 29, 2013, periodic groundwater monitoring will continue as part of the Site's Monitored Natural Attenuation (MNA) and In-Situ Chemical Oxidation (ISCO) programs.

8. Check the appropriate RCRAInfo 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).

X 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 **Wyeth (Pfizer) Pharmaceutical – Rouses Point, NYD002081396, 65 Maple Ave, Rouses Point, NY.** Specifically, this determination indicates that the migration of known or reasonably suspected to be "contaminated" groundwater is under control, and that monitoring will be conducted, as necessary, 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: Daniel J. Eaton Date: 09-29-2016
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