

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action Environmental Indicator (EI) RCRAInfo code (CA725) Current Human Exposures Under Control

Facility Name: Pfizer Rouses Point
Facility Address: 64 Maple Street, Rouses Point, NY 12979
Facility EPA ID #: NYD002081396

BACKGROUND

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EIs) 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 EIs 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 EIs 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 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).

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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?

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

 If no - re-evaluate existing data, or

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

Background

The Site is located at the intersection of Maple Street (to the east) and Academy Street (to the south) in the Village of Rouses Point, Clinton County, New York. The Site is located approximately 800 feet west of the northern end of Lake Champlain and 3,300 feet south of the Canadian border. The Site includes land in the Village of Rouses Point and the Town of Champlain. The Site is zoned I-2, Industrial. The location of the Site is depicted on **Figure 1**.

The Site is currently owned and operated by Pfizer (formerly Wyeth) as a pharmaceutical manufacturing and research facility. The Site contained two operational facilities, the Main Plant (still operational) and the Chemical Development Plant (demolished). The Main Plant (located primarily on the eastern portion of the Site) includes approximately 1 million square feet of manufacturing and supporting infrastructure space. The Main Plant portion of the facility maintains an address of 64 Maple Street. This portion of the Site was previously owned by Wyeth and sold to Akrimax Manufacturing, LLC in 2006, who then leased the plant back to Wyeth (later acquired by Pfizer) for pharmaceutical manufacturing operations. Pfizer re-acquired the Main Plant portion of the facility from Akrimax in 2011 and Akrimax no longer operates at the Site. Operations at the Main Plant include, or formerly included, the manufacturing, primary processing and packaging of over-the-counter and prescription pharmaceuticals (see Figure 1-2).

The Chemical Development Plant property (Chem D) located on the western portion of the Site is owned and was operated by Pfizer. The Chem D facility has included approximately 120,000 square feet of pharmaceutical research and development and warehouse space. The Chemical Development Plant portion of the facility at address of 100 Academy Street was demolished in the winter of 2014/2015.

The Main Plant and Chem D Plant were operated as semi-autonomous units up until the demolition of the Chemical Development Plant. Much of the Site infrastructure was shared between the two plants including steam, process wastewater treatment facilities, and hazardous waste storage. The Main Plant facility includes the manufacturing buildings, boiler house, air treatment buildings, and general Site grounds including the undeveloped portions of the Site.

The Site maintains a 6 NYCRR Part 373 Hazardous Waste Management Permit (NYSDEC Permit # 5-0928-00017/00175) which is currently in a Corrective Action status.

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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			Volatile Organic Compounds (VOCs), Semi-VOCs (SVOCs) and metals.
Air (indoors) ²		X		Multiple VOCs detected in sub slab soils. None exceeded OSHA Permissible Exposure Limits
Surface Soil (e.g., <2 ft)		X		Contaminated surface soils were removed in previous remedial actions
Surface Water		X		There are no surface water bodies on-site.
Sediment		X		There is no known instances of contaminated sediment detected
Subsurface Soil (e.g., >2 ft)	X			Volatile Organic Compounds (VOCs), Semi-VOCs (SVOCs), polychlorinated biphenyls (PCBs), and petroleum related constituents.
Air (outdoors)		X		Air (outdoors) X Contaminant levels in Outdoor Air have not exceeded there criterion values.

_____ 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.

X If yes (for any media) - continue after identifying key contaminants in each

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).

²Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggests 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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“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):

Site groundwater is contaminated with VOCs, SVOCs, and several metals. Soil Vapor Intrusion resulting from contaminated groundwater is not an issue, the results of indoor air testing are well below their respective DOH air quality standards. Multiple subslab depressurization systems have been installed in homes offsite and downgradient from the plant to prevent any potential vapor intrusion as a possible threat to indoor air at offsite residences. Contaminated surface soils were removed during previous remedial actions. Surface water contamination has not occurred as there are no on-site surface water bodies and contaminated groundwater has not migrated far enough to possibly discharge into any off-site surface water bodies. For sediments, contamination has not been detected either on or offsite. Subsurface soils are contaminated with VOCs, SVOCs, a PCB, and petroleum related constituents. There have been no instances where contaminants were found in outdoor air above their respective DOH air quality standards.

Reference(s): 2012 Draft Corrective Measures Study Report, 2011 Progress Report No. 3

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	NO	NO	NO	YES	---	---	NO
Air (indoors)	NO	---	---	---	---	---	
Soil (surface, e.g., <2 ft)	---	---	---	---	---	---	---
Surface Water	NO	NO	---	---	---	---	---
☐ Sediment	---	---	---	---	---	---	---
Soil (subsurface e.g., >2 ft)	---	---	---	YES	---	---	NO
Air (outdoors)	---	---	---	---	---	---	---

Instructions for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors= spaces for Media which are

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

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not “contaminated” as identified in #2 above.

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

_____ 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).

X 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):

Contact with contaminated groundwater is possible with concern to construction workers. For onsite residents/workers contamination is not a concern as there are no potable or non-potable water supply wells on-site as public water is provided to the site and the surrounding town by the Village of Rouses Point. For indoor air there are no complete pathways as the contamination levels of the air are well below their respective DOH air quality standards. However multiple subslab depressurization systems have been installed in homes downgradient from the plant to prevent any vapor intrusion should it occur. For contaminated surface soils there are no pathways completed as the contaminated surface soil of the site was removed during a previous remedial action then covered with clean fill preventing any possible exposure.

For surface water there is no surface water bodies on-site and all off-site surface bodies that have been sampled have not shown any indication of site related contaminant. For sediments there have been no sediments detected with site related contaminants so it is not a concern for this site. For the subsurface soil contaminants are still present and construction workers are at risk with concern to coming into contact with the contaminated subsurface soil. For outdoor air there have been only minor amounts of site related contaminants detected and as such is not a source contamination.

Reference(s): 2012 Draft Corrective Measures Study Report, 2011 Progress Report No. 3

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

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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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 cannot 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.”

X 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):

Contact with groundwater contamination by construction workers could be significant as contamination levels are still high enough to be hazardous to human health. For subsurface soils, levels of contamination are not known so there is the possibility of contaminants being present at levels that could be significant with regards to human health.

Reference(s): 2012 Draft Corrective Measures Study Report, 2011 Progress Report No. 3

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

X 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):

Contamination of construction workers from groundwater is possible but do to the extensive monitoring of the contaminated groundwater plumes the possibility of construction workers being

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exposed to significant levels is less likely. Due to the extensive knowledge of contaminated groundwater provided by monitoring efforts exposures should be within acceptable limits. For subsurface soils the possibility of workers coming into contact with a high concentration area is slim and can be decreased even further by prescreening potential construction sites. Due to the lack of wide spread subsurface soil contamination the chances of significant exposure are found to be within acceptable limits.

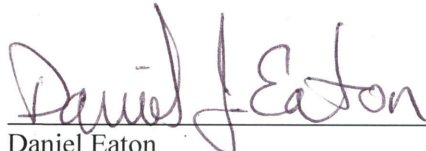
6. Check the appropriate RCRA Info status codes for the Current Human Exposures Under Control EI event code (CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (and attach appropriate supporting documentation as well as a map of the facility):

 X 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 **Pfizer Rouses Point, NYD002081396, 5100018, located at 64 Maple Street, rouses Point, NY 12979** 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.

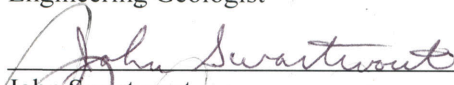
Completed by:


Daniel Eaton

Engineering Geologist

Date: September 30, 2015 ✓

Supervisor:


John Swartwout
Section Chief

Date: September 30, 2015 ✓

Director:


Jim Harrington
Bureau Director, Bureau A

Date: September 30, 2015

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Locations where References may be found:

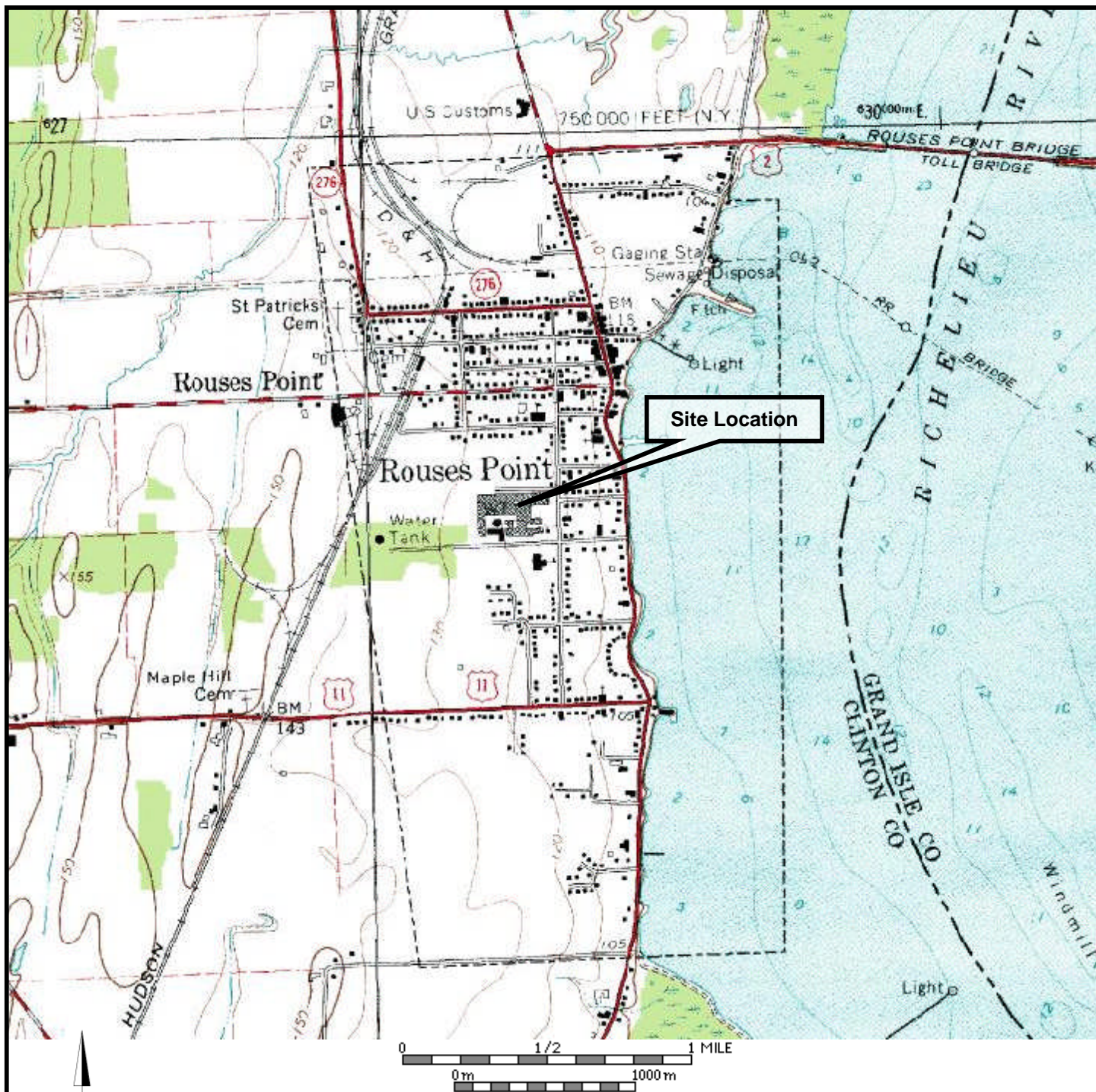
New York State Department of Environmental Conservation, Central Office
Division of Environmental Remediation
625 Broadway 12th Floor
Albany, New York 12233-7013

Contact telephone and e-mail numbers:

Daniel Eaton
New York State Department of Environmental Conservation
625 Broadway, 12th Floor
Albany, NY 12233-7015
daniel.eaton@dec.ny.gov
518-402-9563

FINAL NOTE: THE HUMAN EXPOSURES EI IS A QUALITATIVE SCREENING OF EXPOSURES AND THE DETERMINATIONS WITHIN THIS DOCUMENT SHOULD NOT BE USED AS THE SOLE BASIS FOR RESTRICTING THE SCOPE OF MORE DETAILED (E.G., SITE-SPECIFIC) ASSESSMENTS OF RISK.

FIGURES



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QUADRANGLE LOCATION

Figure 1-1 SITE LOCATION MAP

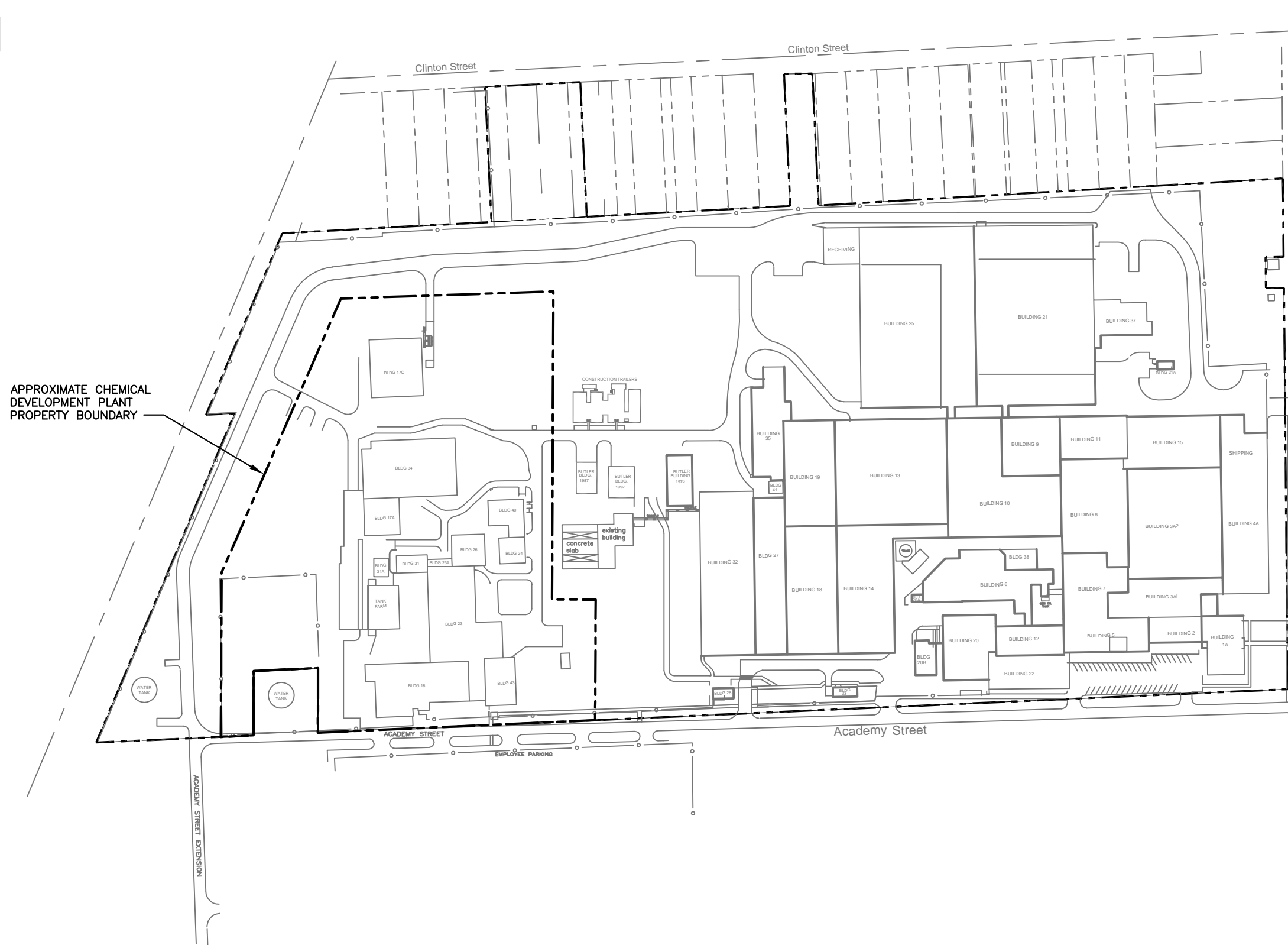
Pfizer, Inc.

Rouses Point, NY



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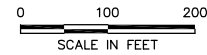
\\chestnut\Projects\206910 Wyeth Rouses Point - Environmental Site Assess\wp\RCRA\CMS\Figures\206910-Fig 2 0610.dwg, Apr. 06, 2012 - 2:38pm



APPROXIMATE CHEMICAL
DEVELOPMENT PLANT
PROPERTY BOUNDARY

LEGEND:

--- APPROXIMATE SITE BOUNDARIES



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PFIZER, INC.
ROUSES POINT, NEW YORK
CORRECTIVE MEASURES STUDY REPORT

JOB NO.: 206910
DATE: APRIL 2012
SCALE: AS NOTED
SHEET: OF

FIGURE 1-2

SITE PLAN

REV	DESCRIPTION	DATE
1	CORRECTION TO BUILDING 43	6/29/07
DESIGNED BY:	JE	CHECKED BY: DW
DRAWN BY:	SH	206910-Fig 2 0610.dwg



709 WESTCHESTER AVENUE, SUITE L2
WHITE PLAINS, NEW YORK 10604
914.448.2266 | www.woodardcurran.com

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