DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA750)

Migration of Contaminated Groundwater Under Control

Facility Name: **Ortho-Clinical Diagnostics**
Facility Address: **1001 US Route 202, Raritan, New Jersey, 08869-0606**
Facility EPA ID #: **NJD068715424**

BACKGROUND

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).

Facility Description

Site Description

Ortho-Clinical Diagnostics (OCD) is an Administration and Manufacturing facility (the site) located at 1001 U.S. Route 202 North in Raritan Borough, Somerset County, New Jersey. The facility manufactures hospital and laboratory reagents used primarily for blood chemistry clinical products, which are usually packaged into "diagnostic kits." The property occupies Lot 4 on Block 31 of the Raritan Borough tax map and encompasses an area of approximately 66 acres. Approximately 9 acres are covered by buildings, 16 acres by roadways, parking lots and other paved surfaces, 11 acres by wooded areas, and 30 acres by landscaped areas. A detailed description of the site and its history is provided in the May 2, 2001 RCRA Facility Investigation Report (RFI Report) (Ref. 2). Security measures at the facility include a chain-link fence, surveillance cameras, and ongoing surveillance by security guards. A Site Layout Map is included as Figure A-1 in Attachment A.

A mix of industrial and residential land usage characterizes the area surrounding the site. Route 202 is located immediately north of the site; the New Jersey Transit Raritan Maintenance Yard is located south and southeast of the site; the former North American Products (NAPA) facility and residential properties are located to the east; and Information Technology Infrastructure Services, a division of Johnson & Johnson Services, Inc., is located to the west. The Raritan Industrial Park is situated south of the New Jersey Transit and south-southeast of the OCD property.

Early development of the site began shortly after Ortho Products, Inc. acquired the site from the Township of Bridgewater at a public auction in 1945. The corporate name of the company was changed to Ortho Pharmaceutical Corporation (OPC), a division of Johnson & Johnson Company (J&J), following the purchase of the property. In December 1973, Ortho Diagnostics Inc. (ODI) was formed from Ortho Pharmaceutical as a separate subsidiary of J&J. From 1972 to 1976, ODI coexisted on the property with Ortho Pharmaceutical. Ortho Pharmaceutical moved its operations to the northern side of Route 202 in 1976. ODI changed its name in July 1980 to Ortho Diagnostic Systems, Inc. (ODSI). Effective January 1, 1998, the name of the facility's operating entity was changed from ODSI to OCD with no change in ownership. Limited information is available regarding OPC's operations at the site prior to their relocation to the northern side of Route 202 in 1976. OPC reportedly conducted research and development activities on veterinary compounds and human medicinals. OCD's activities at the facility, since its onset as ODI in 1973, have historically focused on research and production operations related to transfusion medicine (donor screening and immunohematology) products.

Environmental Setting

The site is relatively flat lying with a slight slope to the south. The site is situated approximately 1.2 miles east of the North Branch of the Raritan River, which flows south to its confluence with the South Branch forming the main branch of the Raritan River. The main branch of the Raritan River flows to the east and is approximately 0.75 miles south of the site. A small drainage ditch transmits stormwater flow southward in the western portion of the site, eventually leading to an unnamed tributary of the Raritan River. Stormwater is conveyed in the eastern and central portions of the site to either the East Storm Sewer Outfall (001) or the West Storm Sewer Outfall (002), respectively. Both of these outfalls discharge into a drainage ditch that runs along the New Jersey Transit railroad tracks, immediately south of the site. A divide in the drainage ditch results in the flow of stormwater toward the west and toward the east, each pathway ultimately leading to an endpoint at the Raritan River.

The site lies within the Piedmont Physiographic Province (Triassic Lowlands) which is characterized mainly by gently rounded lowland hills separated by wide valleys. The site is underlain by the Passaic Formation, which consists of non-marine, reddish-brown mudstone, shale, siltstone, and fine-grained sandstone interbedded with a lesser amount of gray to black siltstone, shale, and mudstone. The strike of the bedrock in the vicinity of the site is due North to N10° W and the dip is approximately 8° to 11° to the east-northeast. Bedrock is encountered at an approximate depth of 3 to 12 feet below grade and is composed predominantly of weathered reddish-brown shale and siltstone. More competent bedrock zones are typically encountered below a depth of 30 feet.

The Passaic Formation is composed primarily of relatively impermeable materials, and derives its water-bearing properties mostly due to secondary porosity in the form of bedding plane fractures, near-vertical joints, and weathered zones within the formation. Two water-bearing zones have been identified at the site during the RCRA Facility Investigation (RFI). The first water-bearing zone typically occurs in the shallow weathered bedrock within a depth of approximately 40 feet. The depth to water in monitoring wells screened within this zone varies from 6 to 28 feet below grade. The predominant groundwater flow direction in the shallow bedrock zone is toward the south. The shallow water-bearing unit appears to be separated from a deeper water-bearing zone by more competent beds in the Passaic Formation as evidenced by a hydraulic head differential of approximately 40 feet between the two zones. The depth to water in monitoring wells screened in the deep bedrock zone ranges from 48 to 67 feet below grade. Where fractures are encountered, the deeper bedrock zone is typically characterized by a higher permeability than the shallower zone.

Groundwater usage in the vicinity of the OCD site has been investigated during various stages of the RFI. A detailed evaluation of groundwater usage concluded that there were no active domestic wells located within a half-mile distance downgradient of the site. The focused well search indicated that all residences were connected to the Elizabethtown Water Company's supply. No public supply wells exist within a one-mile radius of the site. One active industrial supply well was identified at a location within the Raritan Industrial Park, approximately 600 feet south of the OCD property boundary.

Site Regulatory History

Environmental conditions at the OCD site have been evaluated in conjunction with investigative and monitoring activities completed pursuant to regulatory permits issued by the New Jersey Department of Environmental Protection (NJDEP) and the United States Environmental Protection Agency (EPA). A description of the regulatory permits is provided below.

New Jersey Department of Environmental Protection (NJDEP)
NJPDES-DGW Permit

On June 15, 1987, NJDEP Division of Water Resources issued a draft NJ Pollutant Discharge Elimination System – Discharge to Ground Water (NJPDES-DGW) permit (No. NJ0057894) to OCD. The permit required OCD to install groundwater monitoring wells in response to the closure/post-closure of the 10,000-gallon waste methanol UST (SWMU-7). This permit prompted the installation of monitoring wells and the initiation of a quarterly groundwater sampling program to determine the facility's potential impact on the groundwater quality underlying the site. The final NJPDES-DGW permit was issued to OCD on April 4, 1990. As indicated in a NJDEP-DGW Permit modification issued on May 1, 1992, the quarterly groundwater sampling program was expanded to include additional monitoring wells that were installed to address Solid Waste Management Units (SWMUs) identified at the site. Although this permit expired on May 31, 1997, OCD was required by EPA and NJDEP to continue the quarterly groundwater sampling program in accordance with the site's RCRA Corrective Action Program. OCD continues to monitor the groundwater quality at the site on a quarterly basis to evaluate trends in volatile organic compound (VOC) concentrations in groundwater, and additionally, to assess the effectiveness of groundwater remedial efforts initiated at the site in 2004.

Environmental Protection Agency (EPA)

OCD submitted a RCRA Part B application to EPA on December 5, 1984. In response to this application and subsequent data submissions, EPA issued a Hazardous and Solid Waste Amendment (HSWA) permit (NJD068715424) to OCD on September 19, 1988. The HSWA permit became effective on November 15, 1988 and authorized OCD to conduct business as a hazardous waste storage and incineration facility with the following regulated units: one incinerator, two container storage areas, and one aboveground vaulted tank. The four RCRA regulated units were closed as documented in June 5, 1991 correspondence to NJDEP and subsequently delisted by NJDEP in a letter dated July 22, 1991.

A RCRA Facility Assessment (RFA) was completed for the facility in June 1987. The September 19, 1988 HSWA permit also imposed requirements under the RCRA Corrective Action Program that included a RCRA Facility Investigation (RFI), corrective actions relative to the RFI, and minimization of waste generated at the facility. Several phases of investigative work have been completed to characterize environmental conditions at Areas of Concern (AOCs) and the SWMUs. OCD submitted a comprehensive RFI Report to USEPA and NJDEP on May 2, 2001 to summarize all investigative and remedial actions completed between 1995 and 2000. OCD was proactive in initiating an enhanced reductive dechlorination system in 2004 that has been successful in reducing VOC concentrations in groundwater at the site. OCD is in the process of conducting supplemental sampling and investigations to address the regulators' comments that were issued in 2006 in response to the May 2, 2001 RFI Report.

Environmental Conditions

Environmental conditions at the site have been characterized through extensive soil and groundwater sampling conducted over the past 10 years and the extent of soil and groundwater quality impacts have largely been defined (Ref.'s 1, 2, 3, 6, 8, and 13). A total of 13 Solid Waste Management Units (SWMUs) and 16 Areas of Concern (AOCs) have been identified at the OCD site under the RCRA Corrective Action program. The SWMUs and AOCs are shown on Figure A-2 in Attachment A. In addition, groundwater quality on-site and off-site has been investigated and summarized in several reports to USEPA and NJDEP (Ref.'s 4, 5, 9, 11, 14 and 17). Groundwater quality has been monitored on a quarterly basis and the results have been statistically evaluated and summarized in annual reports to the regulators.

OCD has completed several corrective actions to address soil quality impacts within the various SWMUs and AOCs, as summarized in the table below.

Corrective Actions during RCRA Facility Investigation

AOC / SWMU ID	SWMU/AOC Description	Corrective Action
AOC-1	Soil in Basement of Building G	Excavation of fuel oil-impacted soil
AOC-3	Gasoline USTs near Building D	Excavation of petroleum hydrocarbon-impacted soil
AOC-4	Fuel Oil/Motor Oil in Soil Beneath Roadway	Excavation of petroleum hydrocarbon-impacted soil
SWMU-8	Southwest Leach Field/10,000-Gallon Waste Solvent UST	Removal of the former 10,000-gallon waste solvent UST and excavation of surrounding VOC-impacted soil
SWMU-12	550-Gallon Gasoline UST	Removal of the former 550-gallon gasoline UST and excavation of surrounding gasoline-impacted soil
SWMU-13	Process/Sanitary Sewer Line System	Cleaning of manholes and subsequent abandonment of the inactive, off-site process and sanitary sewer lines

In 2004, OCD initiated an enhanced reductive dechlorination (ERD) system to remediate a trichloroethene (TCE) plume in groundwater that extends from the facility in the vicinity of Buildings J and R, southward to the NJ Transit property, located south of the OCD site. The ERD system includes 20 injection wells used for the injection of a dilute molasses/water solution to remediate the TCE concentrations in groundwater. The ERD groundwater remediation program has been successful in reducing TCE concentrations in groundwater at the site since its inception in 2004. A more detailed discussion of these activities is provided in the responses to questions in the remainder of this EI CA750 form.

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 are not available, skip to #8 and enter" IN" (more information needed) status code.

A list of the documents reviewed in preparation of this document is included on the following page and is summarized below.

Groundwater quality on-site and off-site has been investigated and summarized in several reports to USEPA and NJDEP (Ref.'s 1, 2, 3, 6, 8, and 13). Groundwater quality has been monitored on a quarterly basis and the results have been statistically evaluated and summarized in annual reports to the regulators (Ref.'s 4, 5, 9, 11, 14 and 17). The use of enhanced reductive dechlorination to remediate VOC concentrations has been described in report submissions to USEPA and NJDEP (Ref.'s 7, 12, 15 and 18).

References:

(1) 1993 Draft RCRA Facility Investigation Report. Prepared by Dames & Moore. Dated June 30, 1993.

(2) RCRA Facility Investigation Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated May 2, 2001.

(3) Sampling Results for Industrial Well at 2 Johnson Drive. Report prepared by Langan Engineering & Environmental Services, Inc. Dated March 8, 2002.

(4) 2001 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated June 3, 2002.

(5) 2002 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated April 8, 2003.

(6) PDB Results for the April 2003 Groundwater Sampling Event. Report prepared by Langan Engineering & Environmental Services, Inc. Dated July 11, 2003.

(7) Enhanced Bioremediation Pilot Study Report and Full-Scale Design. Prepared by ARCADIS G&M, Inc. Dated July 21, 2003.

(8) Off-Site Groundwater Investigation Results for NJ Transit Property. Report prepared by Langan Engineering & Environmental Services, Inc. Dated December 30, 2003.

(9) 2003 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated April 28, 2004.

(10) RCRA Facility Investigation Report Addendum. Prepared by Langan Engineering & Environmental Services, Inc. Dated October 13, 2004.

(11) 2004 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated February 24, 2005.

(12) Report Addendum on Full-Scale Enhanced Reductive Dechlorination Activities. Prepared by ARCADIS. Dated February 2005.

(13) Off-Site Groundwater Investigation Results for the JFK School Property. Report prepared by Langan Engineering & Environmental Services, Inc. Dated October 20, 2005.

(14) 2005 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated January 23, 2006.

(15) 2005 Report Addendum on Full-Scale Enhanced Reductive Dechlorination Activities. Prepared by ARCADIS. Dated March 2006.

(16) Documentation of Environmental Indicator Determination, EI CA725. Prepared by Langan Engineering & Environmental Services, Inc. Dated September 2006.

(17) 2006 Annual Groundwater Monitoring Report. Prepared by Langan Engineering & Environmental Services, Inc. Dated May 7, 2007.

(18) 2006 Report Addendum on Full-Scale Enhanced Reductive Dechlorination Activities. Prepared by ARCADIS. Dated April 2007.

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

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 "contaminated."

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

Groundwater conditions at the site have been described in the May 2, 2001 RFI Report (Ref. 2). Groundwater is encountered in two distinct zones within the bedrock (Passiac Formation) underlying the site. Because of the shallow depth to bedrock (3 to 12 feet), groundwater is not typically encountered in the thin overburden zone. The Passaic Formation is composed primarily of relatively impermeable materials, and derives its water-bearing properties mostly due to secondary porosity in the form of bedding plane fractures, near-vertical joints, and weathered zones within the formation. The first water-bearing zone occurs in the shallow weathered bedrock within a depth of approximately 40 feet. The depth to water in monitoring wells screened within this zone varies from 6 to 28 feet below grade. Monitoring wells screened within the shallow weathered bedrock zone have a characteristically low yield. Water level measurement data from the shallow bedrock zone are not contoured because the groundwater elevations are highly variable and non-uniform across the site. However, a general evaluation of the groundwater elevations in the shallow bedrock zone indicates a predominant hydraulic gradient toward the south. Other indicators that support the groundwater flow direction toward the south include the TCE plume configuration, the sloping topography toward the south, and the location of the major surface water body (Raritan River) south of the site.

The shallow water-bearing unit appears to be separated from a deeper water-bearing zone by more competent beds in the Passaic Formation as evidenced by a hydraulic head differential of approximately 40 feet between the two zones. The depth to water in monitoring wells screened in the deep bedrock zone ranges from 48 to 67 feet below grade. The monitoring wells in the deep bedrock zone generally extend to depths of 75 to 100 feet. Where fractures are encountered, the deeper bedrock zone is characterized by a higher permeability than the shallower zone. Groundwater flow in the deep bedrock zone is toward the south-southeast, which is consistent with the apparent migration pattern of VOCs in groundwater toward the south-southeast along the bedrock strike. Investigations have shown that potentiometric surface elevations in certain deep bedrock monitoring wells at the OCD site are influenced by pumping at an industrial supply well located approximately 600 feet south of the OCD property boundary. The industrial supply well is located in the Raritan Industrial Park and the pumping of this well is believed to exert an influence on groundwater flow in the deep bedrock zone.

The groundwater quality at the site has been characterized in great detail from quarterly monitoring of existing monitoring wells over the past eight years (Ref.'s 4, 5, 9, 11, 14 and 17), and additionally from a focused groundwater investigation during the RFI as summarized in the May 2, 2001 RFI Report (Ref. 2). Overall, VOC concentrations in the shallow bedrock zone represent the predominant groundwater issue of concern at the site. VOCs in groundwater within the deep bedrock zone are significantly lower in concentration and very limited in extent based on results from groundwater investigations and monitoring at the site (Ref.'s 2, 8, and 17).

[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).

Based on a review of historic groundwater quality data, the primary constituents of concern that have been historically detected in groundwater at concentrations exceeding their NJDEP Class IIA Groundwater Quality Standard (GQS) include: TCE, benzene, vinyl chloride, chloroform, and PCE, with TCE being the predominant compound of concern at the site. The results of the quarterly monitoring at the site over the past eight years are illustrated in Figures B-1 through B-5 in Attachment B. A summary of those compounds exceeding the NJDEP Class IIA GQS during the quarterly sampling conducted in 2006 (the most recent year for which complete results are available) is provided in Table B-1. A review of this data indicates that there are two primary areas of groundwater quality impacts at the site. A third area characterized by chloroform concentrations in groundwater is no longer an issue of concern as chloroform concentrations have declined to levels below the GQS in recent years.

The primary groundwater quality impacts at the site are associated with a TCE plume that has been delineated in the shallow bedrock zone in the south-central portion of the site, extending south from the facility in the vicinity of Buildings J and R (see Figure A-1). The maximum TCE concentration is present in a monitoring well (MW-36) at a location immediately east of Building J, where the highest TCE concentration in 2006 was 22,000 micrograms per liter (ug/L) (Ref. 16). The TCE plume is believed to originate below the OCD facility in the area of Building G, where TCE was historically used as a secondary refrigerant in a lyophilizer, a unit used for freeze-drying to extend the shelf life of manufactured products. The TCE plume extends southward to the NJ Transit property and is delineated by monitoring wells at the JFK School property, located immediately south of NJ Transit and south of the OCD site. The results of groundwater monitoring have not shown any detectable concentrations of TCE nor its degradation products in monitoring wells on the JFK School property (Ref.'s 13 and 17). As described in the 2006 Annual Groundwater Monitoring Report, several additional VOCs have been detected in monitoring wells within the TCE plume at concentrations exceeding their NJDEP Class IIA GQS, although at significantly lower concentrations than TCE. Concentrations of cis-1,2-dichloroethene (cis-1,2-DCE) and vinyl chloride have increased in certain wells since initiation of the remedial injection program in 2004. The presence of cis-1,2-DCE and vinyl chloride is a positive indicator that TCE is being actively degraded in response to the dilute molasses solution injections (Ref.'s 17 and 18). Additional information regarding this area is provided in the response to Question 3 on this EI CA 750 form.

OCD has also completed off-site groundwater investigations to delineate the extent of TCE concentrations in groundwater as summarized in several reports to USEPA and NJDEP (Ref.'s 3, 8, and 13). The off-site well locations are shown on Figure B-1 in Attachment B. TCE has been detected in off-site shallow bedrock monitoring wells (MW-39 and MW-40) south of OCD on the NJ Transit Property, at a distance approximately 320 feet downgradient from the southern OCD property boundary. Analytical results indicate no detections of TCE in monitoring wells (MW-42 and MW-43) on the JFK School property, which are located at distances approximately 600 feet from the OCD southern property boundary and south of NJ Transit.

The highest TCE concentrations in groundwater occur primarily in the shallow bedrock zone. Groundwater quality in the deeper bedrock zone has been characterized through the ongoing monitoring of deep bedrock monitoring wells MW-28Dr, MW-29Dr, MW-34D, and MW-37. As illustrated on Figure C-2 in Attachment C, TCE concentrations in the deep bedrock monitoring wells are either non-detect or at trace levels (1 to 2 ug/L), with the exception of deep bedrock monitoring well MW-29Dr. TCE concentrations in MW-29Dr demonstrate an overall downward trend as shown on the graph in Figure C-2, where the maximum TCE concentration (84 ug/L) was detected during 2001 and the minimum TCE concentration (29 ug/L) was detected recently during the fourth quarter of 2006. OCD installed an off-site deep bedrock monitoring well (MW-41D) on the NJ Transit property during 2003 to characterize groundwater quality in the deep bedrock zone down-gradient of MW-29Dr. OCD presently conducts annual groundwater monitoring of monitoring well MW-41D. As indicated on Figure B-4 in Attachment B, only trace concentrations of TCE (2.8 ug/L to 3.9 ug/L) were detected in MW-41D during the first two annual sampling events in 2005 and 2006. At the time MW-41D was installed in 2003, TCE was detected at concentrations of 3.9 ug/L and 1.4 ug/L (Ref. 8). A slightly higher TCE concentration of 11 ug/L was detected in the industrial supply well located southeast of OCD, which is shown on Figure C-2 (Ref. 3). The active pumping of the industrial supply well at 2 Johnson Drive likely captures TCE-impacted groundwater in fractured bedrock from multiple industrial sources in the immediate area, which is known to be regionally impacted by TCE (Ref. 2).

A second more localized area of groundwater quality impacts is located in the southwestern portion of the site in the area of the former 10,000-gallon waste solvent underground storage tank (UST), identified as SWMU-8 (see Figure A-2). The 10,000-gallon waste solvent UST was removed in 1997, along with VOC-impacted soil that surrounded the former UST. The groundwater quality impacts in the southwestern portion of the site are localized to the area of MW-32 and consist of variable, yet persistent concentrations of benzene. TCE, PCE, and vinyl chloride have also been detected in this portion of the site at concentrations exceeding the NJDEP Class IIA GQS. The maximum VOC concentrations detected in this area of the site during 2006 were: 69 ug/L of benzene, 33 ug/L of vinyl chloride, 6.9 ug/L of TCE, and 4.7 ug/L of PCE (Ref. 17). Additional information regarding this area is provided in the response to Question 3 on this EI CA 750 form.

The third area of historic groundwater quality impacts (no longer considered an issue of concern) is located in the central portion of the site, south of Building J. As shown on Figure A-2, this area of the site was designated as AOC-11, in response to the historical detection of chloroform in two monitoring wells (MW-20 and MW-35) at concentrations exceeding the NJDEP Class IIA GQS. Chloroform concentrations in MW-20 and MW-35 have attenuated significantly over the past several years, and chloroform concentrations are either non-detectable or well below the NJDEP Class IIA GQS. Additional information regarding this area of concern is provided in the response to Question 3 on this EI CA 750 form.

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

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)?

__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.

As discussed in the previous section, three areas of groundwater quality impacts were identified at the site:

(1) TCE Plume
(2) Groundwater Quality Impacts at SWMU-8 (Former 10,000-Gallon Waste Solvent UST)
(3) Former Chloroform Groundwater Quality Impacts at AOC-11

As described below, chloroform is no longer an issue of concern as chloroform concentrations in groundwater are now below the NJDEP Class IIA GQS.

TCE Plume

As described in the following section, TCE concentrations have declined considerably since initiation of the groundwater remedial program at the site by ARCADIS in 2004.

The primary groundwater quality issue at the site is the TCE plume located in the south-central portion of the facility. TCE was discovered in groundwater during routine sampling of monitoring wells at the site in the early- to mid-1990's. The source of the TCE was originally believed to be related to a former leach field, that was reportedly active at the site between 1956 and 1966. Results from the RCRA Facility Investigation (RFI) indicated that the leach field was not the source of the TCE. A detailed groundwater investigation was conducted in 1998 that was effective in delineating the extent of TCE in the shallow bedrock zone, and identifying a source of the TCE. The results from the 1998 RFI indicated that TCE likely originated from a lyophilizer unit that was formerly housed in the basement of Building G (see Figure A-1). The distribution of TCE in the wells located within and downgradient of the source area since 1999 is depicted on Figure B-4 in Attachment B. The highest TCE concentration detected in an on-site monitoring well to date is 56,000 ug/L in well MW-36, the well located nearest to the source area. TCE was also detected in off-site monitoring wells (MW-39 and MW-40) that were installed in 2003 to investigate the down-gradient extent of the plume. The highest TCE concentration detected in an off-site monitoring well to date is 48 ug/L (well MW-39). Two additional off-site monitoring wells (MW-42 and MW-43) were installed on the JFK School property downgradient of the site during August 2005. No volatile organic compounds (VOCs) were detected in the monitoring wells on the school property thereby providing horizontal delineation of the TCE plume in the shallow bedrock zone (Ref.'s 13 and 17). (See Figure C-2 in Attachment C.)

[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.

In 2004, OCD initiated remedial actions to address the TCE plume through implementation of an Enhanced Reductive Dechlorination (ERD) system. The ERD system is based on the injection of a dilute molasses/water solution to create an anaerobic and reducing environment in which TCE is degraded to harmless end-products. A pilot test of the ERD technology was first conducted in 2002 to: (1) determine whether the technology was feasible at the site; and, (2) collect site-specific design parameters for a full-scale system. As part of the ERD pilot test, two injection wells and three injection monitoring wells (IW-1, IW-2, IMW-1, IMW-2 and IMW-3) were installed at the site.

Based on a successful pilot study, full-scale bioremediation activities were implemented in January 2004. During January 2004, 18 additional injection wells (IW-3S through IW-20S) were installed to supplement the two injection wells installed during the pilot test. The full-scale system was designed to focus treatment on the portion of the plume with TCE concentrations exceeding 10 ug/L, with the injection wells oriented in four transects within this area (see Figure C-1 in Attachment C). The injection wells are screened in the shallow bedrock zone. Full-scale dilute molasses injections commenced in April 2004 utilizing a total of 20 injection wells. OCD continued the full scale ERD remedial system in 2006, with the injection of a dilute molasses/water solution during four separate events. During 2006, total of 13,975 gallons of the dilute molasses/water solution was injected into 14 of the 20 injection wells. Based on the successful reduction of TCE concentrations in the distal portion of the plume, as described below, the last two injection events focused solely on the TCE source area in the vicinity of monitoring well MW-36.

Overall, results from the groundwater monitoring program indicate decreasing TCE concentration trends in the majority of wells in response to the injections performed as part of the enhanced bioremediation program. As illustrated in Figure C-2 and Graphs C-1 to C-5 in Attachment C, the most noticeable decline in TCE concentrations in response to the enhanced bioremediation injections is evident for wells MW-14r, MW-21r, MW-27r, MW-34, and MW-35 in the shallow bedrock zone. The significant decline in TCE concentrations in MW-14r, MW-21r, MW-27r, MW-34, and MW-35, since initiation of the enhanced bioremediation injections is further illustrated in the following table and on Figure C-3 in Attachment C, which illustrates annual mean TCE concentrations since 1999:

Mean TCE Concentration in Groundwater (ug/L)

Well	2003	2004	2005	2006
MW-14r	20.3	4.9	2.3	0.5
MW-21r	24	15	8	2.3
MW-27r	43	1.2	ND	ND
MW-34	207	208	48	5.2
MW-35	15	7.7	5.7	2.4

ERD injections were initiated in April 2004

Concentrations of the secondary compounds of concern (benzene, PCE and vinyl chloride) in the on-site wells have also exhibited similar declines in concentration or have remained stable at relatively low concentrations since initiation of the bioremediation program (see Figure C-3).

TCE concentrations have also showed a decreasing trend in deep bedrock monitoring well MW-29Dr located on the downgradient property boundary since initiation of full-scale remediation as illustrated in Figure C-2. Mean annual TCE concentrations in MW-29D have decreased from 64 ug/l in 2003 to 40 ug/L in 2006 (see Figure C-3). As illustrated on Figure C-2 in Attachment C, TCE concentrations in the other deep bedrock monitoring wells are either non-detect or at trace levels (1 to 2 ug/L). The trace concentrations of TCE (1.4 to 3.9 ug/L) detected in the most distant deep bedrock monitoring well (MW-41D) have also remained stable.

Although TCE concentrations in source area monitoring well MW-36 have remained relatively stable since remediation began, they have shown a significant overall decline since 1999 (see Figures C-2 and C-3). Mean annual TCE concentrations in MW-36 have decreased from 39,750 ug/l in 1999 to 19,500 ug/L in 2006, indicating an overall reduction in source mass. Furthermore, the production of TCE degradation products in MW-36 (most notably cis-1,2-DCE, see Figure C-3) confirms that active degradation of TCE is taking place in the source area in response to the dilute molasses injections.

The success of the remediation program in reducing overall TCE concentrations is further illustrated on Figure C-1, which provides a comparison of the on-site distribution of TCE in 1999 (pre-remediation) and 2006 (post-remediation). As shown on Figure C-1, the full-scale injection system has reduced TCE concentrations to less than 10 ug/L throughout the entire on-site plume outside the source area. Furthermore, approximately 50% of the on-site plume (outside the source area) currently has TCE concentrations of less than 1 ug/L, most notably in the central portion of the plume where the injection program has been focused up to this point. Remedial activities in 2007 are focused on optimizing the molasses injection strategy (volume, concentration, and frequency) to specifically target areas with TCE concentrations currently above 1 ug/L, including adjacent to and downgradient of MW-36.

Based on the data evaluation presented above, implementation of the ERD remedial system has significantly reduced TCE concentrations downgradient of the source area, resulting in a dramatic decrease in plume size and distribution. The data also indicate that the source mass is being depleted and that the remediation program has accelerated this process. Future remedial activities will focus on addressing elevated TCE concentrations within the source area. Groundwater quality in the TCE plume area will continue to be monitored to ensure that the TCE concentrations continue their downward trend and do not rebound.

With the continued operation of the ERD remedial system and its network of injection wells (the IW-series wells) and the observed decreasing trends in the monitoring wells (as discussed above), it is reasonable to consider the TCE plume to be stabilized (or decreasing) within the footprint configuration depicted in Figure C-1 in Attachment C.

Groundwater Quality Impacts at SWMU-8 (Former 10,000-Gallon Waste Solvent UST)

As previously summarized, localized groundwater quality impacts exist at monitoring well MW-32, which is located immediately down-gradient of a former 10,000-gallon waste solvent UST. The UST and surrounding VOC-impacted soils were removed in June 1997 (Ref. 2). The extent of groundwater quality impacts in this area are defined by five wells, including MW-32 which serves as a source area well located approximately 15 feet downgradient of the former UST, and four downgradient monitoring wells (MW-15r, MW-16r, MW-22r and MW-25r). The locations of these wells are shown on Figure A-1.

The constituents of concern detected in these wells at concentrations exceeding NJDEP Class IIA GQS include benzene, and to a lesser extent, vinyl chloride, TCE and PCE, with the highest concentrations detected in well MW-32. The concentration trends in groundwater for these VOCs in the area of SWMU-8 are shown on Figures B-1 and B-3 through B-5 in Attachment B, Figure C-3 in Attachment C, and Graphs C-6 through C-8 in Attachment C.

A review of Graph C-8 indicates that benzene concentrations in MW-32 have declined considerably since 2004, although concentrations still remain above the NJDEP Class IIA GQS. As shown on Figure C-3, the mean benzene concentration in MW-32 has decreased from 250 ug/L in 2004 to 34 ug/L in 2006. In addition, the concentrations of vinyl chloride, TCE, and PCE have also consistently declined in MW-32 since 2004 (see Graph C-7), although they also remain above their NJDEP Class IIA GQS. During this timeframe the mean concentration of vinyl chloride has declined from 28 ug/l in 2004 to 14 ug/l in 2006, the mean TCE concentration has declined from 12 ug/l in 2004 to 4 ug/l in 2006 and the mean PCE concentration has declined from 6.8 ug/l to 2.2 ug/l during this time-frame (see Figure C-3).

A review of the data for MW-16r, located approximately 40 feet downgradient of the source area, indicates that the concentrations of benzene have consistently declined since 2003, with the annual mean concentration declining from 6.2 ug/l in 2003 to non-detect in 2006 (see Figures B-1 and C-3 and Graph C-8). Concentrations of vinyl chloride in this well have remained relatively stable since 2002, ranging from non-detect to concentrations slightly exceeding its NJDEP Class IIA GQS of 1 ug/l (see Figures B-5 and C-3). Finally, TCE and PCE have not been detected in this well at concentrations exceeding their NJDEP Class IIA GQS since 2003, with neither compound detected in 2006 (see Figures B-3, B-4 and C-3).

A review of the data for downgradient monitoring wells MW-22r, MW-15r and MW-25r, located 80 feet, 140 feet and 180 feet downgradient of the source area, respectively, indicates that benzene and vinyl chloride have not been detected in MW-22r or MW-25r since 1999, with concentrations in MW-15r either being non-detect or slightly above their NJDEP Class IIA GQS (see Figures B-1, B-5 and C-1). Furthermore, TCE and PCE have not been detected in these wells since 1999, except for one instance of TCE at a concentration slightly exceeding its Class IIA GQS (1.8 ug/l versus 1 ug/l) in MW-25r in 2001 (see Figures B-3, B-4 and C-3).

Based on the data presented above, which indicates declining concentrations near the source area (as exhibited by wells MW-32 and MW-16r) and either not-detectable or consistently low concentrations downgradient of the source area (as exhibited in wells MW-15r, MW-22r and MW-25r), the VOC plume at SWMU-8 is very localized, and shows no indication of down-gradient migration over time (i.e., the plume is stable). Furthermore, VOC concentrations are anticipated to continue to naturally attenuate over time.

Former Chloroform Groundwater Quality Impacts at AOC-11

As summarized in the supporting information for the responses to Questions 1 and 2, elevated concentrations of chloroform were previously detected in a localized area of the site to the south of Building J, where MW-20r and MW-35 are located (as illustrated on Figure B-2). Historically, chloroform was detected in these wells at concentrations exceeding its NJDEP Class IIA GQS of 6 ug/L. In November 2005, NJDEP revised the Class IIA GQS for chloroform from 6 ug/L to 70 ug/L. Since revision of the GQS in 2005, there have been no detections of chloroform at concentrations exceeding the 70 ug/L NJDEP Class IIA GQS.

Furthermore, as illustrated on Figures B-2 and C-3, the historically elevated chloroform concentrations in MW-20r and MW-35 have declined significantly over time. Chloroform concentrations in MW-20r have declined from a historic high of 480 ug/L in 2002 to non-detectable levels during the two sampling events conducted in 2006. The decline of chloroform concentrations in MW-20r is illustrated on Graph C-9 in Attachment C. Chloroform concentrations in MW-35 have declined from a historic high of 3,300 ug/L in 1999 to non-detectable levels in 2006. The decline of chloroform concentrations in MW-35 is illustrated on Graph C-10 in Attachment C. Finally, it should be noted that chloroform has not been detected at concentrations exceeding its NJDEP Class IIA GQS in any other wells located on the site, including those immediately down-gradient of MW-20r and MW-35, with a majority of these wells containing no detectable concentrations of chloroform over time.

Based on the data presented above, the extent of chloroform impacts to groundwater in this area of concern has been limited to the area immediately adjacent to and surrounding wells MW-20r and MW-35, with no downgradient migration of the plume at concentrations exceeding its NJDEP Class IIA GQS. Furthermore, the significant decline in chloroform concentrations over time in these two wells, with the most recent data from 2006 indicating either non-detectable or minimal concentrations of chloroform, indicates that the presence of chloroform in groundwater is no longer a concern.

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)
Page 4

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

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

__X__ 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):

As referenced in the response to Question 1 in this EI CA750 form, the only surface water drainage feature at the site is a very shallow drainage ditch located considerably west of the areas of known groundwater quality impacts (see Figure A-1). Consequently, there is no risk of discharge of VOC-impacted groundwater to surface water bodies at the site. Furthermore, as illustrated in Figure C-2, the TCE plume is delineated by off-site monitoring wells MW-42 and MW-43 located on the JFK School Property, and the TCE plume does not intersect any off-site surface water body. The nearest surface water body to the site is an unnamed tributary to the Raritan River, which is located approximately 900 feet south of the site, and immediately southwest of the JFK School as shown on Figure C-2. The unnamed tributary discharges to the Raritan River approximately 0.75 miles south of the site. The groundwater analytical data from off-site monitoring wells MW-42 and MW-43, located between the site and the unnamed tributary, do not indicate the presence of TCE or related compounds. Consequently, the off-site groundwater monitoring results indicate that the TCE plume is not discharging to the unnamed tributary, or any other surface water body downgradient of the site. Furthermore, the successful ongoing remediation of the TCE plume in groundwater at the OCD site, coupled with natural attenuation mechanisms, is expected to continue the downward trend of TCE concentrations in groundwater immediately down-gradient of the OCD site.

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

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)?

.

___ 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 and Reference(s):

Not Applicable

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

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be **"currently acceptabl**e" (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 acceptabl**e") - 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):

Not Applicable

[4] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) water bodies.
.

Migration of Contaminated Groundwater Under Control Environmental Indicator (EI) RCRIS code (CA750)

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?"

__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 and Reference(s):

As part of its ongoing groundwater remediation and monitoring program, OCD will continue to implement a groundwater monitoring program at the site for the foreseeable future. The purpose of this monitoring will be to confirm the ongoing effectiveness of the remediation program in reducing TCE concentrations in groundwater and confirm that VOC concentrations continue to decline in groundwater underlying the site. OCD will continue to summarize the groundwater monitoring results in annual reports to EPA and NJDEP.

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

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).

_X_ 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 **Ortho-Clinical Diagnostics** facility, EPA ID # **NJD068715424,** located at **1001 US Route 202, Raritan, New Jersey**. 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: _____ Date: _____

Richard P. LoCastro, P.G.
Project Manager

Reviewed/Mdified by: _____ Date:_____

Clifford Ng, RPM
New Jersey Section
RCRA Programs Branch
US EPA Region 2

_____ Date:_____

Barry Tornick, CHMM, Chief
New Jersey Section
RCRA Programs Branch
US EPA Region 2

Approved by: Signed:_____ Date: 9/25/2007

Adolph Everett, P.E., Chief
RCRA Programs Branch
US EPA Region 2

Locations where references may be found:

References reviewed to prepare this EI determination are identified after each response. Reference materials are available at U.S. EPA, Region 2.

Contact telephone numbers and e-mail:

Clifford Ng
(212) 637-4113
ng.clifford@epa.gov

List of Attachments