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

Facility Name: **Westcode, Inc.**
Facility Address: **90 Great Valley Parkway, Frazer, Pennsylvania 19355**
Facility EPA ID #: **PAD071451389**

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

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 "Current Human Exposures Under Control" EI

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

Relationship of EI to Final Remedies

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

Duration / Applicability of EI Determinations

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

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

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		No known/documented releases to groundwater from historical operations.
Air (indoors)[2]		X		No known/documented releases to soil/groundwater from historical operations.
Surface Soil (e.g., <2 ft)		X		No known/documented releases to soil from historical operations.
Surface Water		X		No unpermitted releases of hazardous wastes to the storm water drains are known or suspected to have occurred during historical operations.
Sediment		X		No documented discharges to sediment. No known releases to sediment.
Subsurf. Soil (e.g., >2 ft)		X		No known/documented releases to soil from historical operations.
Air (outdoors)		X		No known releases at the facility.

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

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

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

Rationale and Reference(s):
Westcode, Inc. (Westcode or facility) operated at 90 Great Valley Parkway (Building 4) within the Great Valley Corporate Center in Frazer, Chester County, Pennsylvania from September 1979 until June 1989, when the company moved to Malvern, PA. The facility consists of a single building situated on 5.6 acres, approximately 90 percent of which are covered with impermeable surfaces (asphalt parking areas, concrete walkways, and building footprints), and the remaining

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

[2] Recent evidence (from the Colorado Dept. of Public Health and Environment, and others)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.

area is grass or tree-covered. The facility manufactured and assembled railroad freight car brake valves and transit car components and subassemblies. The manufacturing process included a small electroplating operation and associated metal cleaning and preparation operations. Process areas at the facility included a treatment area containing electroplating process and wastewater treatment tanks, a process chemical storage area, and a waste drum storage area. The process chemical storage and treatment tank areas were located in the northeastern corner of the building

Centocor purchased the facility in September 1989 and completely renovated the interior of the building to accommodate its biological processes. While still owned by Centocor, the facility is currently operated by Janssen Biotech, Inc. (Janssen) for the production of Remicade®, a human protein that is utilized to treat pain and inflammation. Janssen is a large quantity generator of hazardous waste in total at its properties in the Great Valley Corporate Center, but produces only one 55-gallon drum per month of bioreactor cleanout liquids consisting of water, acetone and methanol at the former Westcode property.

Four potential solid waste management units (SWMUs) were identified in an Environmental Priorities Initiative Preliminary Assessment (EPI-PA), dated August 10, 1990: the waste drum storage area, the below-grade spill tank, the sludge dewatering tank, and the treatment/storage tank. All four of the potential SWMUs were located in the northeastern corner of the building.

SWMU 1 - Waste Drum Storage Area: The waste drum storage area was located immediately south of the treatment area. A single layer of drums containing spent solvents, electroplating sludges and other ignitable or corrosive wastes was shown stored along the wall in Westcode's August 1983 Part A Hazardous Waste Permit Application. The drums were stored directly on the concrete floor. The building itself provided additional containment for this area.

SWMU 2 - Below-grade Spill Tank: A 4-foot by 4-foot by 4-foot below-grade spill tank was located outside the northeastern corner of the building. The below-grade spill tank serviced the process chemical storage area.

SWMU 3 - Sludge Dewatering Tank: The sludge dewatering tank that contained electroplating sludges was located in the former treatment area. At the time of its operation, the treatment area was situated on a concrete floor and was surrounded by an approximately 1-foot high concrete berm and the concrete walls of the building.

SWMU 4 - Treatment/Storage Tank: The treatment/storage tank that contained electroplating sludges, plating bath wastes, and spent stripping and cleaning bath solutions was also located in the former treatment area described above.

During Westcode's operation at the facility, no spills, discharges or dumping of any types of hazardous waste were reported. The SWMU's listed above, with the exception of the Below-grade Spill Tank, are known to have been removed from the facility prior to Westcode vacating the property in June 1989. The approximate locations of the former interior SWMUs were observed during an EPA site visit on February 13, 2013. The former waste drum storage area was located within a portion of what is now the loading dock. The process chemical storage area was located in what is now the water room. The former treatment area could not be completely observed because it is a process area that required gowning training for access. This area was viewed through the windows of the entry door. All of the areas within the building were exceptionally clean, as required for Jannsen's biopharmaceutical processes

The area where the below-grade spill tank was reportedly located was also observed during the February 13, 2013 site visit. There was no evidence that the tank was still in place at that location and no piping to the spill tank on the either the interior or exterior walls of the building was observed. The area where the below-grade spill tank was located was grass-covered and no stressed vegetation was observed. Janssen representatives had no knowledge of the tank's existence or fate.

Groundwater

The facility is underlain by Conestoga Series soil, a deep, well drained silt loam with moderate permeability that developed from calciferous schist, micaceous limestone, or marble. The rocks in the area range in age from Precambrian to Ordovician and are mostly metamorphosed sediments, but include large amounts of igneous rocks The Elbrook formation consists of a light blue to gray, finely laminated, fine-grained marble, containing some interbeds of dolomite and limestone. The formation has a moderate porosity and moderate to high permeability. Solution channels provide secondary porosity of moderate magnitude. The expected direction of shallow groundwater flow is to the north toward the north branch of Valley Creek.

Groundwater has never been monitored at the facility as a release of hazardous constituents is neither documented nor suspected. The facility is provided potable water through the Aqua Pennsylvania Main System. There are no known potable water wells on the property or within the Great Valley Corporate Center. Sanitary and storm sewers are provided by the Valley Forge Sewer Authority (VFSA).

Air (Indoor)

The site is essentially capped with structures/pavement. Subsurface soils or groundwater are not suspected to have been contaminated by Westcode operations with constituents that would create vapor intrusion issues into the on-site or neighboring buildings. There are no known or documented releases to subsurface media. Accordingly, no vapor intrusion issues have been identified at the facility.

Surface/Subsurface Soils

The former Westcode operations were conducted inside of the facility's building. There were no known releases to soil at the facility. Approximately 90 percent of the facility is covered by structures and pavement thereby eliminating the potential for exposure to contaminated soil, if any exists. Accordingly, no issues related to soil quality have been identified at the facility.

Surface Water/Sediment

Surface water runoff from the facility is collected by VFSA storm drains that outfall to either Valley Creek located approximately 1,750 feet southeast of the facility or Cedar Hollow Run, a tributary to Valley Creek, located approximately 2,000 feet north of the facility. Cedar Hollow Run joins Valley Creek approximately 1.6 miles east/northeast of the facility. No unpermitted releases of hazardous wastes to the storm water drains are known or suspected to have occurred during Westcode's operations. Processed wastewaters from the facility during Westcode's period of operation were discharged directly to the VFSA via permit. Janssen operates an elementary neutralization unit for pH adjustment of wastewater generated from the production of Remicade®. The neutralized wastewater is discharged under permit to the VFSA. Therefore, there are no known or suspected releases to surface water or sediment.

Air (Outdoor)

There are no records indicating that the facility generated any outside air emissions during its period of operation. A release of contaminants from the facility to outdoor air is not suspected.

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

Summary Exposure Pathway Evaluation Table

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

Instructions for Summary Exposure Pathway Evaluation Table

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

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

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

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

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

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

Rationale and Reference(s):

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

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

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

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

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

Rationale and Reference(s):

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

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

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

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

Rationale and Reference(s):

[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.

6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI event code (CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (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 **Westcode, Inc.** facility, EPA ID # **PAD071451389**, located at **90 Great Valley Parkway, Frazer, Pennsylvania 19355** under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

_____ NO "Current Human Exposures" are NOT "Under Control."

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

Completed by (signature) [signature] Date 6/24/13

(print) Andrew Clibanoff 6/24/13

(title) _____

Supervisor (signature) [signature] Date 6-26-13

(print) Paul Gotthold

(title) Associate Dir, PA Rem (CD)

(EPA Region or State) Region 3

Locations where References may be found:

USEPA Region III
Land and Chemicals Management Division
1650 Arch Street
Philadelphia, PA 19103

PADEP
South East Regional Office
2 E. Main Street
Norristown, PA 19401

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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.