

## **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: **Johnson & Johnson Pharmaceutical Research and Development, LLC**  
Facility Address: **McKean and Welsh Roads, Spring House, Pennsylvania 19477**  
Facility EPA ID #: **PAD000731471**

---

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?

- 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)**  
 Page 2

2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be **“contaminated”<sup>1</sup>** 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)?

	<u>Yes</u>	<u>No</u>	<u>?</u>	<u>Rationale/Key Contaminants</u>
Groundwater		X		No record of contamination.
Air (indoors) <sup>2</sup>		X		No record of contamination.
Surface Soil (e.g., <2 ft)		X		Contaminated soil removed. Attainment of Statewide Health Standards (SHS) demonstrated. No further action determination issued by the Pennsylvania Department of Environmental Protection (PADEP).
Surface Water		X		No record of contamination.
Sediment		X		No record of contamination.
Subsurf. Soil (e.g., >2 ft)		X		Contaminated soil removed. Attainment of SHS demonstrated. No further action determination issued by PADEP.
Air (outdoors)		X		No record of contamination.

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.

---

<sup>1</sup> “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).

<sup>2</sup> Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest 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.

**Current Human Exposures Under Control  
Environmental Indicator (EI) RCRIS code (CA725)**  
Page 3

**Rationale and Reference(s):**

Johnson & Johnson Pharmaceutical Research and Development, Limited Liability Company (LLC) (J&J PRD or facility) owns and operates an active research and development (R&D) facility that occupies a 170-acre grassy campus at the corner of McKean and Welsh Roads, southeast of the Route 309 and Route 63 intersection. The area is a mixed residential/commercial community known as Spring House (deemed a Census Designated Place [CDP] and not an incorporated community). Residential property is located west, north, and east of the facility. Additionally, golf courses are located to the northeast and southeast of the facility. A YMCA was recently constructed directly northwest of the McKean Road entrance to the facility. Route 309 abuts the facility's southwest property boundary, beyond which is Dow Chemical (formerly Rohm and Haas, Inc. or RH), another pharmaceutical research facility. (Note: A brief review of the adjacent Dow Chemical [former RH] facility and its possibility of environmentally impacting the J&J PRD facility were conducted. In 1986, a release of chlorinated solvents that impacted groundwater occurred at the neighboring RH facility. Contaminated soil was removed and the groundwater was treated to remove trichloroethene [TCE], tetrachloroethene [PCE], and total 1,2-dichloroethene [DCE] over a six year period [1990 through 1996]. The 1996 Environmental Indicator [EI] for the RH facility states that contaminated groundwater had not migrated beyond the RH facility property boundaries. The May 2010 EI status update for the RH facility states that the concentrations of chlorinated solvents [primarily PCE and TCE] identified in groundwater at the RH facility have remained low, and that the groundwater plume is stable and remains within the RH facility property boundaries. Groundwater monitoring at downgradient monitoring wells is ongoing at the RH facility.)

Access to the J&J PRD facility is via two separate entrances, one on McKean Road and one on Welsh Road. Access to the property is unrestricted during operating hours. Gates are present at each entrance to the facility, which are closed after operating hours. Building entrances are secured through access via electronic key cards. The facility has 24-hour manned security.

The facility consists of a series of interconnected two, three, and four story buildings that are divided into the administration, commons, engineering, manufacturing, research (Building 41), and drug safety and evaluation (DSE) areas. The majority of the buildings were constructed in 1980 and 1981. Day-to-day administrative duties (e.g., executive offices, accounting, marketing, technical services, and dining areas) are conducted in the administrative and commons areas. The facility's seldom-used natural gas boilers and water softening equipment for the public water influent are located in the basement of the engineering area. The manufacturing area is primarily vacant since the cessation of the manufacturing operations in 2004. R&D is carried out on all four floors of the research area and the fourth floor of the DSE area. The facility's hazardous waste storage areas are located in the research area (Building 41). The facility's pathological waste incinerator was located on the second floor of the DSE area; however, it was dismantled in 1993.

In 2006, the building that houses the main wastewater equalization/neutralization process was constructed east of the fire pond. In 2007, a new four-story research building (Building 42) was constructed. This building consists primarily of laboratory space. Several boilers and a wastewater equalization/neutralization system that handles only wastewater generated in Building 42 are located on the first floor. In addition, three of the facility's aboveground storage tanks (ASTs) are situated in the 4,000 square foot AST containment building located approximately 210 feet southwest of the research area (Building 41).

A man-made fire pond that is approximately one acre in area by 10 feet deep is located 135 feet north of the administration area. The facility's Preparedness, Prevention, and Contingency (PPC) Plan dated October 1, 1991, states that the water in the fire pond is derived from surface water runoff at the facility and direct discharges of shallow groundwater. There is a gate-controlled discharge from the pond which is periodically released to a small, unnamed intermittent stream located approximately 300 feet north of the pond via a drainage pipe that is connected to a spillway. Other miscellaneous site features include a softball field and tennis courts located on the northern corner of the property. A guest house was formerly located in this area. The PPC plan states that a water supply well was located at the guest house which was used occasionally. The guest house was demolished in 2003. At the time of a site visit that took place on October 22, 2010, facility representatives stated there are no wells on the property. A sanitary sewer pump station near the eastern corner of

**Current Human Exposures Under Control  
Environmental Indicator (EI) RCRIS code (CA725)**  
Page 4

the property accepts treated wastewater and sanitary waste from the facility and nearby residences.

Approximately 25 percent of the property consists of impermeable surfaces such as the facility buildings and asphalt/concrete parking areas, access roads, and loading areas. The remaining 75 percent of the property is grass-covered or landscaped, which includes the one acre fire pond and a small wetland area on the east side of the property.

Prior to 1977, the property consisted of two parcels of agricultural land. In 1979, J&J PRD purchased the land and began construction on the property in 1980. According to a letter dated March 16, 1993, the facility was operated by McNeil Pharmaceutical (later referred to as Ortho-McNeil Pharmaceutical [Ortho-McNeil]); however, the facility was always owned by the parent company, J&J PRD. On January 3, 2005, J&J PRD assumed complete operation of the facility from Ortho-McNeil. J&J PRD continues to own and operate the facility at this location.

The 170 acre Spring House campus is currently home to three R&D firms, including J&J PRD (developer of small molecule drugs or tablets), Centocor (developer of large molecule drugs or injectables), and Cordis (developer of stents for cardiac patients). Centocor and Cordis belong to the J&J PRD family of companies. J&J PRD manages all wastes streams from all three firms operating at the facility.

Operations conducted at the facility have consisted of laboratory-scale R&D and manufacturing of pharmaceuticals. R&D, which has included chemical synthesis, analytical chemistry, drug metabolism, toxicology, biochemistry, and pharmacology, was conducted on all four floors of the research area (Building 41) and the fourth floor of the DSE area. In 2007, J&J PRD constructed a new four-story, 215,000 square foot research center known as Building 42. Building 42 houses the R&D operations from the recently closed Exton and Cranberry facilities. R&D is conducted on the second through fourth floors, while the first floor houses mechanical space and a waste equalization/neutralization for the building.

Small quantities of virgin solvents and chemicals are stored in the laboratories. Bulk storage of virgin solvents and chemicals prior to laboratory use was previously on the fourth floor of the research area (Building 41). Currently, there are two main raw materials storage areas located at the facility. Small volume reagents (100 milliliters or less) are stored in bins in climate-controlled glass front cabinets on the first floor of Building 42. Raw solvents are stored inside of locked fireproof cabinets on the first floor of Building 41. The bottles in which the materials are stored are polycoated which reduces the chance of spills if the bottles are dropped (the bottle will not shatter). Both of the storage areas were clean and well-maintained during the October 22, 2010 site visit.

Manufacturing processes that included formulation, preparation, and packaging of PANCREASE® brand pancrelipase capsules were conducted on the first floor of the manufacturing area beginning in 1983. The facility ceased manufacturing of pancrelipase capsules sometime in 2004 and is in the process of dismantling the associated equipment. The facility is currently operating only as a R&D facility.

The facility operates as a large quantity generator (LQG). Previous waste inspections specifically indicated the following wastes were generated at the facility: methanol, methyl ethyl ketone (MEK), ethyl acetate, isopropanol, methylene chloride, chloroform, sulfuric acid, hydrochloric acid, xylene, and cyanide. Other wastes listed on the original Part A Hazardous Waste Permit Application dated November 18, 1980, in addition to those already listed included: acetone, dimethyl benzene, ethyl ether, ethylene dichloride, 2-propanone, toluene, benzene, and mercury. Incinerator ash and baghouse dust also were generated at the facility. The waste materials were typically drummed and shipped off-site for disposal. The facility formerly operated a closed-loop distillation unit to reclaim small quantities of xylene from water for reuse in the laboratories.

Typical wastes currently generated at the facility primarily consist of waste solvents and wastewater. Non-hazardous buffers and salts, and biological and infectious wastes (generally research animal carcasses) also are generated at the facility. Wastes generated by all entities operating at the facility are managed by J&J PRD.

**Current Human Exposures Under Control  
Environmental Indicator (EI) RCRIS code (CA725)**  
Page 5

Eight solid waste management units (SWMUs) have been present during the history of the facility. The following table provides details on the eight SWMUs.

SWMU No.	SWMU Name	Description	Status
1	Drummed Solvent Storage Area	A 24- by 48-foot room located in the research area (Building 41) used to temporarily store waste chemicals and raw products.	Storage capacity of this space was expanded in 2008. No visual evidence of spills or releases and no reported releases.
2	Solvent Drum Storage Area	Area consisting of a concrete floor and cinderblock walls adjacent to two baghouse particulate collectors in an enclosed, open-air courtyard located in the northern corner of the former manufacturing area. Used to store waste solvents (that included isopropyl alcohol and Fast Dry [mineral spirits, methylene chloride, and PCE] used for equipment cleaning) and virgin solvents.	Taken out of service in 2004 with the cessation of manufacturing operations. No visual evidence of spills or releases was observed, and none were reported.
3	Waste Solvent Storage Tank	6,000-gallon underground storage tank (UST) (Tank 006) used to collect waste solvent from the former manufacturing building. Located approximately 250 feet north of the former manufacturing building in a grassy common area.	Removed July 2004. No visual evidence of spills or releases was observed, and none were reported. Currently grass-covered and landscaped.
4	Aqueous Waste Storage Tank	3,000-gallon fiberglass UST (Tank 005) utilized for the collection of wastewater generated in the chemical development laboratory located in the research area (Building 41).	Excavated and replaced in February 1990 with an AST (Tank 013A). Contaminated soil was excavated during closure of the UST. Currently grass-covered. No visual evidence of releases in the area of the former UST or AST.
5	Research Animal Unit Incinerator	Also known as the pathological waste incinerator. Located on the second floor of the facility's DSE area. Utilized to burn animal carcasses, tissue, paper, and other trash generated in this unit.	Operated from 1981 until it was shutdown and dismantled in December 1992. At the time of the 1989 Preliminary Assessment (PA), there were no signs of releases. During the 2010 site visit, the exact location of the incinerator could not be identified.
6	Trash Incinerator	Located in the northwestern corner of the engineering area, the incinerator (also known as the municipal waste incinerator) was utilized to burn non-hazardous waste including cardboard and plastic.	Operated from 1983 until it was shutdown and dismantled in January 1993. At the time of the 1989 PA, there were no signs of releases.
7	Manufacturing Building Baghouse	Located in an open-air courtyard in the northern corner of the former SWMU 2, SWMU 7 consisted of two baghouses that captured dusts	Removed from service in 2004 with the cessation of manufacturing activities and physically removed from the facility between 2005 and 2010.

**Current Human Exposures Under Control**  
**Environmental Indicator (EI) RCRIS code (CA725)**  
 Page 6

		generated by the manufacturing building mixers, compressors, and encapsulation equipment.	Currently, the area is empty, and no visual evidence of releases exists.
8	Catalytic Incinerator Baghouse	Located with the catalytic incinerator in an open-air courtyard on the northeastern side of the former manufacturing building. Vaporized spray-coating solvent (a formulation of isopropyl alcohol and ethyl acetate) containing suspended particles was passed through the baghouse for collection and the vapors were sent to the incinerator.	Removed from service in 2004 with the cessation of manufacturing activities. The baghouse was physically removed from the facility between 2005 and 2010. Currently, the area is empty with the exception of the catalytic incinerator, and no visual evidence of releases exists.

Multiple USTs and ASTs have been in use at the facility as shown on the table below. According to UST closure documentation and confirmed by facility representatives during the 2010 site visit, all USTs have been removed at the facility. In addition, several ASTs have recently been removed at the facility as shown on the table below. There are currently six ASTs in use at the facility.

Tank No.	Capacity Gallons	Contents	Status
<b>USTs</b>			
001	40,000	No. 2 Fuel (Heating) Oil	Removed March 1991
002	10,000	No. 2 Fuel (Heating) Oil	Removed May 1991
003	1,000	Gasoline	Removed January 1992
004	550	Diesel	Removed January 1992
005	3,000	Wastewater Mixture (SWMU 4)	Replaced February 1990 by 013A
006	6,000	Aqueous Waste Solvent (SWMU 3)	Replaced September 1990 / Removed July 2004
007	4,000	Ethyl Acetate	Replaced September 1990 / Removed July 2004
008	6,000	Isopropyl Alcohol	Replaced September 1990 / Removed July 2004
009	550	Diesel	Removed March 1990
010	1,000	Gasoline	Removed April 1998
<b>ASTs</b>			
010A	300	Diesel	Installed January 1983
011A	1,000	Gasoline	Installed April 1998 Removed February 2007
012A	275	Diesel	Installed December 1989 Removed August 2007
013A	3,000	Aqueous Wastewater (SWMU 4)	Installed February 1990 Removed November 2008
014A <sup>(1)</sup>	6,000	Diesel	Installed May 1991

**Current Human Exposures Under Control**  
**Environmental Indicator (EI) RCRIS code (CA725)**  
 Page 7

015A	20,000	No. 2 Fuel (Heating) Oil	Installed May 1991 Back-up fuel for boilers
016A	20,000	No. 2 Fuel (Heating) Oil	Installed May 1991 Back-up fuel for boilers
017A	1,000	Gasoline	Installed May 1991 Removed January 2007
018A <sup>(1)</sup>	2,500	Diesel	Installed May 2003
019A <sup>(1)</sup>	1,750	Diesel	Installed November 2009

<sup>(1)</sup>Currently registered with PADEP.

**Groundwater:** Beginning in 1990, the facility implemented a replacement/closure program for its USTs. All of the USTs were ultimately removed from the facility by 2007, and remedial actions were conducted at several of the UST sites. In addition, several spill response actions have been conducted at the facility since 2003, most of which were issued No Further Action (NFA) determinations under Land Recycling and Environmental Remediation Standards Act (Act 2). There have been several documented releases to soil at the facility, mostly associated with the USTs and conveyance lines. It has been documented, with PADEP concurrence, that groundwater was not impacted resulting from these releases. Therefore, it is concluded that groundwater is not known to be contaminated.

**Indoor Air:** Several releases of fuel oils (gasoline, diesel fuel, and heating oil) and other chemical constituents have historically occurred to soil in the area of various USTs and underground conveyance lines located at the facility as discussed in previous sections of this report. However, these releases have been remediated (via excavation and off-site disposal of contaminated soil) and granted NFA determinations by PADEP. Clean fill material was placed in the excavations following these removal actions. Available documentation indicates that the chemicals of interest analyzed in soil and/or groundwater following these removals were either non-detect or below appropriate Act 2 medium specific concentrations (MSCs). PADEP formally acknowledged that no further remedial actions were necessary following these removals and that groundwater was not impacted.

Because contaminated soil was removed and replaced with clean fill and groundwater is not expected to be impacted, there is not expected to be a potentially complete exposure pathway to on-site workers or off-site receptors via inhalation of volatile constituents in soil and/or groundwater to indoor air.

**Soil:** Contaminated soil was identified during the removal of several the facility's USTs in the 1990s. In addition, there were three reported releases (two fuel oil and one urea solution) at the facility that resulted in the removal of contaminated soil. Post-excavation soil sampling conducted at each of the UST and release areas showed that the contaminated soil was removed. Available records indicate that PADEP has issued NFA determinations for remediated soils in the UST areas. Remediation conducted at the three release areas has demonstrated attainment of the residential or non-residential SHS under the Act 2 program. Therefore, it is concluded that surface and subsurface soils are not known to be contaminated.

**Surface Water:** The facility formerly held a National Pollutant Discharge Elimination System (NPDES) permit for discharges from the fire pond to a nearby stream; however, this permit was superseded by a no exposure certification issued in 2006. The NPDES permit is no longer active and the no exposure certification is valid through November 2011. The facility's operations (including the ASTs) are contained entirely within the on-site buildings. Accordingly, no direct discharges to nearby surface water bodies are expected. Therefore, it is concluded that surface water is not known to be contaminated.

Furthermore, it has been stated that groundwater directly discharges to the on-site fire pond, and shallow groundwater flow is expected to be to the northeast toward the intermittent stream. Documented remedial actions resulting from releases of fuel oils and other chemical constituents conducted throughout the property suggest that groundwater is not impacted by past or current facility operations. Therefore, it is concluded that no controls are relevant for the discharges

**Current Human Exposures Under Control**  
**Environmental Indicator (EI) RCRIS code (CA725)**  
Page 8

of groundwater to the nearby surface water bodies.

**Outdoor Air:** The facility previously operated two permitted incinerators for municipal waste and pathological waste. The municipal waste incinerator was dismantled in January 1993. The pathological incinerator was dismantled in December 1992. In addition, several other emissions sources (e.g., PANCREASE® process, catalytic oxidizer, large scale synthesis center) were removed from the facility in 2004 and 2008. The majority of the permitted emissions sources are associated with the facility's boilers, diesel fired emergency generators, and activities conducted in the R&D laboratories. The facility's air emissions sources are operated under TVOP 46-00027. There have been no recent violations of the facility's permits. The last inspection was completed on April 30, 2010 during which the facility was in compliance. Therefore, it is concluded that no contamination is present for the outdoor air exposure pathway.

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

Contaminated Media	<u>Residents</u>	<u>Workers</u>	<u>Day-Care</u>	<u>Construction</u>	<u>Trespassers</u>	<u>Recreation</u>	<u>Food</u> <sup>3</sup>
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 some settings and should be added as necessary.

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).

If yes (pathways are complete for any "Contaminated" Media - Human Receptor combination) -

---

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

**Current Human Exposures Under Control  
Environmental Indicator (EI) RCRIS code (CA725)**  
Page 9

---

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):**

**Current Human Exposures Under Control**  
**Environmental Indicator (EI) RCRIS code (CA725)**  
Page 10

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be “**significant**”<sup>4</sup> (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):**

---

<sup>4</sup> 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.

**Current Human Exposures Under Control**  
**Environmental Indicator (EI) RCRIS code (CA725)**  
Page 11

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):

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 **Johnson & Johnson Pharmaceutical Research and Development, LLC** facility,

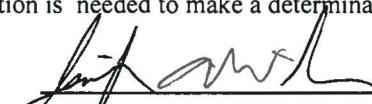
EPA ID # **PAD000731471**, located at **McKean and Welsh Roads, Spring House, Pennsylvania 19477**

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)



Date 1/13/12

(print)

Jennifer A. Wilson, P.G.

(title)

Licensed Professional Geologist

Supervisor (signature)



Date 1/13/2012

(print)

Mohamad Mazid, Ph.D., P.E.

(title)

Chief, Engineering Services

(EPA Region or State) PADEP, Southeast Regional Office

2-15-12

Locations where References may be found:

USEPA Region III  
Waste and Chemical Mgmt. Division  
1650 Arch Street  
Philadelphia, PA 19103

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

Contact telephone and e-mail numbers  
(name) Jennifer A. Wilson, P.G.  
(phone #) 484-250-5744  
(e-mail) jewilson@pa.gov

**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.**