

US EPA ARCHIVE DOCUMENT

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:	Eli Lilly and Company, Clinton Laboratories
Facility Address:	10500 South State Road 63 Clinton, IN 47842
Facility EPA ID #:	IND 072 040 348

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).

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2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be **“contaminated”**¹ above appropriately protective risk-based “levels” (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

	<u>Yes</u>	<u>No</u>	<u>?</u>	<u>Rationale / Key Contaminants</u>
Groundwater	x			
Air (indoors) ²		x		
Surface Soil (e.g., <2 ft)		x		
Surface Water		x		
Sediment		x		
Subsurf. Soil (e.g., >2 ft)	x			
Air (outdoors)		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.

X 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): On-site ground water contamination: 1,2-DCA 9.4 ppb (max); 1,1,2-TCA 100 ppb (max); trichlorofluoromethane 12 ppb (max.). Residual VOCs in soil at former UST sites and at a solvent recovery plant. 1,1,2-TCA, methylene chloride, toluene and methanol detected.

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) 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.

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

Summary Exposure Pathway Evaluation Table

Potential **Human Receptors** (Under Current Conditions)

"Contaminated" Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food ³
Groundwater	_no__	_no__	---	---			---
Air (indoors)	---	---	---				
Soil (surface, e.g., <2 ft)	---	---	---	---	---	---	---
Surface Water	---	---			---	---	---
Sediment	---	---			---	---	---
Soil (subsurface e.g., >2 ft)				_no__			no_
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.

X_____ 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) - 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):

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be

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

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“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):

⁴ If there is any question on whether the identified exposures are “significant” (i.e., potentially “unacceptable”) consult a human health Risk Assessment specialist with appropriate education, training and experience.

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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):

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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 _Eli Lilly & Co., Clinton Laboratories_____ facility, EPA ID # _IND 072 040 348__, located at Clinton, Indiana_____ 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 5-11-99
 (print) Donald A. Heller
 (title) Environmental Scientist

Supervisor (signature) _____ Date 5-11-99
 (print) Hak K. Cho
 (title) Chief, IL/IN/MI Section
 (EPA Region or State) Region 5

Locations where References may be found:

Phase 1 RFI Sampling Reports, Quarters 1-4, Radian International, 1998-9

Building C-4 Soil Investigation, ATC Associates, 10-2-98

UST Farms Closure Reports, AWD Technologies, 1993

UST Farms Closure Reports, WW Engineering and Science, Inc., 1993

Contact telephone and e-mail numbers

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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.

DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION

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

Migration of Contaminated Groundwater Under Control

Facility Name:	Eli Lilly and Company, Clinton Laboratories
Facility Address:	10500 South State Road 63 Clinton, Indiana 47842
Facility EPA ID #:	IND 072 040 348

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?

☒ 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 "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).

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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?

☒ 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.

Rationale and Reference(s): On-site ground water contamination: 1,2-DCA 9.4 ppb (max) (MCL 5); 1,1,2-TCA 100 ppb (max) (MCL 5); trichlorofluoromethane 12 ppb (max). Concentrations were measured in samples taken from high-volume production wells on-site. References are RFI sampling reports, Quarters 1-4, 1998-9, Radian international.

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).

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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)?

☒ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the “existing area of groundwater contamination”²).

☐ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the “existing area of groundwater contamination”²) - skip to #8 and enter “NO” status code, after providing an explanation.

☐ If unknown - skip to #8 and enter “IN” status code.

Rationale and Reference(s): Four quarters of RFI ground water sampling and water level measurements indicate that 6 on-site high capacity production wells induce a facility-wide cone of depression. This appears to have kept contaminated ground water contained on-site, where it is extracted and pumped to the facility WWTP. However, a risk assessment and predictive study will be necessary, to account for residual soil contamination, in a scenario in which the production wells are not in operation; i.e., natural ground water flow conditions.

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.

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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): The facility is located about 1,500 feet from the Wabash River; but there is no evidence that ground water contamination discharges into it, as long as the production wells are operating.

References: Phase 1 RFI reports, Quarters 1-4, 1998-9, Radian International.

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5. Is the **discharge** of “contaminated” groundwater into surface water likely to be “**insignificant**” (i.e., the maximum concentration³ 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 concentration³ 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 concentration³ 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 concentrations³ 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):

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

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6. Can the **discharge** of “contaminated” groundwater into surface water be shown to be “**currently acceptable**” (i.e., not cause impacts to surface water, sediments or eco-systems that should not be allowed to continue until a final remedy decision can be made and implemented⁴)?

_____ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site’s surface water, sediments, and eco-systems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR 2) providing or referencing an interim-assessment,⁵ appropriate to the potential for impact, that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment “levels,” as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

_____ If no - (the discharge of “contaminated” groundwater can not be shown to be “**currently acceptable**”) - skip to #8 and enter “NO” status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or eco-systems.

_____ If unknown - skip to 8 and enter “IN” status code.

Rationale and Reference(s):

⁴ Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

⁵ The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

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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?”

☒ 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): Upstream and downstream samples from the Wabash River may be collected. A facility-wide risk assessment and predictive study will be calculated. Two of the six production wells have shown contamination and must be monitored.

