



Human Health and Ecological Risk Assessments

In this Pines Update....

This *Pines Update* provides information about the human health risk assessment and the ecological risk assessment that will be completed for the Area of Investigation. These two risk assessments are the next step in the process following the completion the Remedial Investigation. *Pines Update* No. 6 (February 2005), available at www.pinesupdate.com, provides a general description of all the steps of the investigation process being conducted in the Area of Investigation.

Conservative/Protective: Dealing with Uncertainty in the Risk Assessments

You will hear the risk assessments referred to as being conservative. In this case, “conservative” means health protective. That is, the data, assumptions, and judgments used in the risk assessments are selected to produce risk estimates that may overestimate rather than underestimate risks. This ensures that the resulting estimated risks, even with some uncertainty, are protective of human health and the environment.

Northern Indiana Public Service (NIPSCO) and Brown Inc. (Brown) are conducting an investigation of the nature and occurrence of coal combustion by-products in the Area of Investigation, located in the vicinity of the Town of Pines, Indiana. The investigation activities follow the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This Act (and its corresponding guidance) provides procedures for environmental investigations. *Pines Updates* No. 11 through 17 (available at www.pinesupdate.com) detailed the Field Investigation activities and provided progress reports on those activities. The Field Investigation is complete, and the draft Remedial Investigation Report has been submitted to the US Environmental Protection Agency (USEPA) and the Indiana Department of Environmental Management (IDEM).

Upon USEPA approval of the Remedial Investigation Report, the Human Health Risk Assessment and the Ecological Risk Assessment will be completed. These two risk assessments are the formal process of estimating human health and ecological risks due to exposures to constituents in environmental media. The assessments are based on the information presented in the Remedial Investigation Report. This *Pines Update* discusses in more detail how risk is evaluated in the two risk assessments.

What is Risk?

Risk can be defined as the likelihood (or probability) that a given exposure to a hazard will lead to a harm. We encounter risks everyday, and make an assessment of risk frequently. We often act based on our assessment of risk, sometimes quickly, like whether to turn left now or wait for an on-coming car to pass, other times more deliberately, like changing to a heart-healthy diet.

For risk to exist, there must be both a hazard and an exposure. If there is a hazard without an exposure, or an exposure without a hazard, there is no risk.

A **hazard** is present where materials or a situation have the ability to cause harm or another adverse affect. Examples of hazards are:

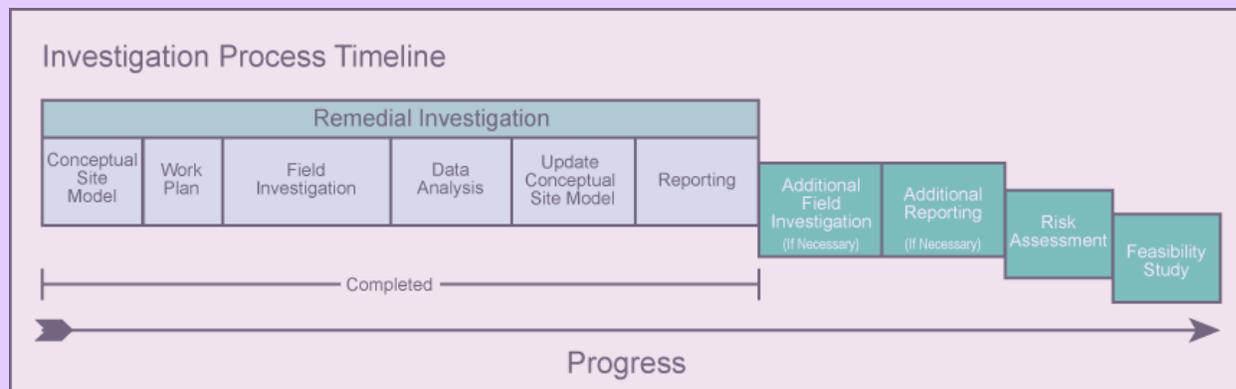
- Traffic
- Lightning
- Ingredients in household cleaning products and other commonly-used materials
- A release of gasoline from a storage tank at a gas station
- X-rays and other medical imagining procedures

An **exposure** is a situation where a hazard can impact or influence a receptor (humans, wildlife, or plants). Examples of exposures are:

- Crossing the street
- Being outdoors during a thunderstorm

Where do the Human Health and Ecological Risk Assessment fit in the RI/FS Process?

For the Pines Area of Investigation, the Remedial Investigation Report was submitted to the US Environmental Protection Agency and the Indiana Department of Environmental Management on May 19, 2008. The Risk Assessment Reports are due 90 days after the Remedial Investigation Report is approved by the USEPA.



- Using household or other products in an inappropriate manner
- Sampling the release from the gasoline storage tank at a gas station without proper personal protective equipment
- Getting a dental x-ray

Hazards and exposures must be linked before there is a risk. For example, if there is heavy traffic (a hazard) and you cross the street (an exposure) there is a risk. On the other hand, if there is no traffic (no hazard) and you cross the street (an exposure), or if there is heavy traffic (a hazard) and you do not cross the street (no exposure), there is no risk.

Risk can range from miniscule to great. We encounter risks all of the time, and often address them by taking actions to minimize our hazard or exposure, or both. We are used to encountering and accepting risks and we often do so without much concern. For example, household cleaning products contain hazardous substances like chlorine in bleach, yet when used and handled sensibly and as directed by the manufacturer, the risk is negligible and no harm occurs. However, if accidentally swallowed by a young child, there is a potential risk, which depends on how much is swallowed and whether it happened once or multiple times. Also, gasoline contains benzene, which has been proven to cause cancer in humans under certain conditions, yet we are exposed to benzene when we fill our gas tank. Dental x-rays and other x-rays as well as MRIs and other medical imaging procedures expose us to low levels of radiation, but individuals routinely undergo such procedures. The way we address risk when there is a potential for harm (i.e., because both a hazard and an exposure are present) is to evaluate the chance or likelihood of harm that the situation presents.

In summary, risk is the presence of both a hazard and an exposure that combine for a chance or likelihood to lead to harm. Risks can be reduced or avoided by reducing or eliminating either the hazard or the exposure or both, but most commonly we encounter and survive risks all of the time (we cross the street).

What is a Risk Assessment?

A risk assessment is a procedure for estimating the amount of potential risk where both a hazard and an exposure are present. For the Area of Investigation, two risk assessments will be conducted, a Human Health Risk Assessment and an Ecological Risk Assessment. These two Risk Assessments will follow USEPA requirements and guidance for risk assessments. They will examine the likelihood of potential harm from exposure to constituents derived from coal combustion by-products in the Area of Investigation.

- The Human Health Risk Assessment will estimate the risk of potential adverse human health affects.
- The Ecological Risk Assessment will estimate the risk for potential adverse affects on wildlife and plants.

Many factors are used in a Risk Assessment to calculate the estimated risk, including data, assumptions, and judgments. To account for uncertainties in some of the factors used, Risk Assessments are conducted to be conservative (refer to text box on Page 1), producing results which are purposely biased so that they overestimate rather than underestimate potential risk.

How is a Risk Assessment Conducted?

The Human Health Risk Assessment will estimate the potential risk to humans, and the Ecological Risk Assessment will estimate the potential risk to wildlife and plants. While these assessments are conducted by different types of professionals and each has somewhat different methods, the basic principles are the same. They both come down to the basic concept of hazard combined with exposure can present a risk, or very simply:

$$\text{Hazard} + \text{Exposure} = \text{Risk}$$

The Hazard Element of a Risk Assessment

The results of research and studies conducted worldwide and over years are used as the basis for determining what particular affects might be caused by a particular constituent. For the Area of Investigation, the most up-to-date information on coal combustion by-product-derived constituents will be used.

Probably one of the most important factors in understanding the hazard element of a risk assessment is the dose, which is the amount of a constituent taken into an organism at a given time. A dose of one or two aspirin is therapeutic, whereas an entire bottle of aspirin can be lethal. In addition to the size of the dose, the number of doses, and the time over which the doses are taken are important considerations.

The Exposure Element of a Risk Assessment

In conducting the Risk Assessments for the Area of Investigation, the exposure element of risk will be represented by exposure pathways through which constituents may move from coal combustion by-products to humans, wildlife or plants. The most common exposure routes are:

- Eating or drinking (the ingestion route)
- Breathing (the inhalation route)
- Contact with the skin (the dermal contact route)

For the Area of Investigation, a Conceptual Site Model has been developed to identify how humans and wildlife might come into contact with constituents of coal combustion by-products through each of the three routes of exposure. The Conceptual Site Model represents current understanding of where suspected coal combustion by-products exist in the Area of Investigation and how they might travel from one place to another. The Conceptual Site Model is a “work in progress” that is updated based on new information; for example, the location of suspected coal combustion by-products has been refined as the Visual Inspections were completed (see Pines Update No. 17, September 2007, available at www.pinesupdate.com). The analytical data collected during the Field Investigation indicates the amounts of constituents.

Each way that humans or wildlife might contact constituents derived from coal combustion by-products is called an exposure pathway. An exposure pathway is complete, if four conditions are met:

- There must be a source of coal combustion by-product-derived constituents and a release of the constituents to the environment;
- There must be a mechanism by which the constituents can be transported to an environmental medium (e.g., from the source to air, water, or soil);
- There must be a point where humans, wildlife, or plants can come in contact with the environmental media; and
- There must be an exposure route in operation at the contact point (e.g., inhalation, ingestion, dermal contact).

In the Area of Investigation, fill containing suspected coal combustion by-products has been used in several areas. The Risk Assessments will determine whether or not there are locations in the Area of Investigation where humans, wildlife, or plants may contact the environmental media where suspected coal combustion by-product-derived constituents are present, and how and whether there is an exposure route in operation at the locations.

What are the steps in the Human Health Risk Assessment?

The Human Health Risk Assessment for the Area of Investigation will consist of a four-step process.

Step 1 – Constituents of Potential Concern will be Identified from Data Collected and Evaluated

The first step of the process is to identify the constituents that will be evaluated in the Human Health Risk Assessment. To do this, the analytical data collected in the Area of Investigation for all constituents are compared to established conservative Federal and State risk-screening levels. Those constituents present at concentrations above the screening levels are considered “constituents of potential concern,” and will undergo further assessment. Because a constituent is above the conservative screening levels, does not mean it poses an unacceptable potential risk, but because it is above the conservative screening level, it undergoes the Human Health Risk Assessment process.

Step 2 – Exposure Assessment

The second step is the exposure assessment, which consists of identifying complete exposure pathways, or ways that humans come in contact the constituents of potential concern in the Area of Investigation. Consideration will be given to both how humans might come into contact with constituents of potential concern currently, and how humans might contact constituents of potential concern in the future.

Step 3 – Hazard Assessment

In this step, toxicity data for the identified constituents of potential concern is obtained from USEPA and other Federal and State agencies.

Step 4 – Characterizing Risk

The final step is to combine the results of previous steps to estimate the overall potential risk at the Area of Investigation. In this step, possible potential adverse effects from exposure to the individual constituents of potential concern are evaluated. The estimated potential risk is expressed differently for constituents of potential concern that may cause cancer and those that do not (see Text Box, *What’s the Risk to Me?*)

What are the steps in the Ecological Risk Assessment?

The Ecological Risk Assessment estimates potential risk to plants and animals. This assessment is conducted in 3 steps, described below.

Step 1 – Identify Receptors and Constituents of Potential Ecological Concern

The first step in the Ecological Risk Assessment is to define its objectives and its scope. An analysis is required to determine what ecological receptors need to be evaluated in the Ecological Risk Assessment. The analysis starts with identifying and studying the habitats present in the Area of Investigation, and which of these habitats may be influenced by constituents derived from coal combustion by-products. Next, the types of species (receptors) found in those habitats are identified and studied regarding how they might come in contact with the suspected coal combustion by-product derived constituents. Once this is accomplished, then (similar to the Human Health Risk Assessment) the constituents of potential ecological concern are identified by comparing concentrations of constituents detected in the Area of Investigation to federal and state risk screening levels. Constituents consistently present in the Area of Investigation at concentrations above these screening levels are evaluated in the Ecological Risk Assessment.

Step 2 – Risk Analysis

The risk analysis step evaluates the potential for plants and animals to be exposed to constituents of potential ecological concern, and characterizes the potential effects of any exposure.

- The exposure assessment evaluates the possible harmful effects from being exposed to the individual constituents of concern. This step includes estimating or measuring the amount of a constituent in soil or aquatic media, and then evaluating ecological receptor exposure to these constituent concentrations.
- The ecological effects assessment is conducted to quantitatively link concentrations of constituents of potential concern to adverse effects in receptors. Literature reviews of results of field studies and toxicity test can provide information on what concentration of a constituent is associated with a certain adverse effect.

What's the Risk to Me?

The Human Health Risk Assessment does not estimate the potential risk to any specific person. It is an estimate of risk based on a prescribed set of procedures, which are described in this update. Risk to a particular individual depends not only on any environmental exposure, but also on exposures to the same constituents from everyday activities, health and lifestyle choices, and genetics.

For the Human Health Risk Assessment, risk estimates are expressed differently for noncarcinogens (constituents that may cause adverse effect other than cancer) and carcinogens (constituents that may cause cancer).

For **noncarcinogens**, estimated exposures are compared to a reference dose (RfD). The RfD is developed by USEPA scientists and is an estimate of the amount of a material a person (including the most sensitive person) could be exposed to on a daily basis over a lifetime without developing noncancer adverse health effects. A comparison of the exposure estimate to the RfD establishes a Hazard Index (HI). An HI greater than 1 suggests that an adverse effect is possible.

For **carcinogens**, risk estimates are expressed in terms of probability. For example, exposure to a particular carcinogen over an estimated lifetime of 70 years may present a 1 in 10,000 chance of causing cancer. This risk estimate can also be expressed as 1×10^{-4} . The USEPA acceptable risk range for carcinogens is within 1×10^{-4} to 1 in 1,000,000 (1×10^{-6}). It is important to note that the American Cancer Society estimates the background cancer rate in the US at approximately 1 in 2 for men and 1 in 3 for women. Therefore, regulating exposures at these very low risk levels is very protective of public health.



Step 3 – Risk Characterization

In the final step, the results of the previous steps are analyzed to estimate the likelihood of potential adverse effects to ecological receptors in the Area of Investigation. The Risk Characterization process compares the results of the exposure assessment and the results of the ecological effects assessment to determine if receptors are currently exposed to constituents of potential concern at levels that might cause potential adverse effects, and whether future exposure is likely. If potential adverse ecological effects are predicted, the types, extent, and severity of the potential adverse effects are determined.

What will the results of the Risk Assessments be used for?

The Human Health Risk Assessment and the Ecological Risk Assessment are an important part of the Remedial Investigation process. The two Risk Assessments compile the data collected during the Remedial Investigation, and evaluate the data using USEPA approved procedures to produce an objective determination of potential risks in the Area of Investigation. The risk assessments are very conservative by design (refer to text box on Page 1). The assumptions made in each step of the risk assessment processes -- the risk screening levels used in the assessments, the exposure assumptions made, and the toxicity values used -- are very conservative, and may overestimate potential risk rather than underestimate it. The results of the Risk Assessments help determine what if any potential risks might exist that should be reduced or eliminated.

In the Area of Investigation, a water service extension in portions of the Town of Pines eliminated potential risks associated with well water. The two Risk Assessments will be used to evaluate in part whether this early remedial action is sufficiently protective or if any additional actions should be taken. If the Risk Assessments indicate that additional actions might be necessary to address potential risks, the Feasibility Study will evaluate a range of measures that could be taken.

Our Commitment....

NIPSCO and Brown are committed to keeping you informed on the progress of the investigation of the Pines Area of Investigation. Look for future *Pines Updates* to update you to our progress. We also have a website to provide continual updates on the project:

www.pinesupdate.com

Please contact the Communications Coordinator at the address listed below to be placed on the mailing list.

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