

ENVIRONMENTAL RISK PROFILE PHARMACEUTICAL INDUSTRY

A risk profile is a structured management tool for identifying the various exposures associated with an operation. Typically, a risk profile will encompass a review of an organization's operations with a focus on administrative strategies / protocol for reducing or managing particular risks. Environmental risk should not be exempt from this process. In fact, many organizations create stand-alone Environmental Risk Profiles (ERPs) to specifically address the area of environmental liability. This process adds to an organization's ability to systematically identify environmental risk and effectively manage it. Below is an excerpt from an ERP for Pharmaceutical Industry, which identifies some major exposures. A completed ERP can show the impact such exposures can have on the organization, as well as the risk management strategies available.

Pharmaceutical Industry confront environmental liability every day. Specifically, they face environmental exposures in three major areas: operational, transportation and disposal liabilities. Each area must be explored to identify risks that may expose the organization to environmental liability. This hypothetical ERP identifies some of the major exposures and associated claims.

EXPOSURES

OPERATIONAL EXPOSURES

- Liability arising both on- and off-site from historical use, such as improper disposal, underground tanks, residual contamination from small leaks or spills, etc.
- Liability associated with local or regional soil / groundwater contamination, regardless of the source of contamination.
- Environmental liability associated with products sold to third-parties:
 - · Agricultural products
 - · Medicine and other healthcare products
 - Research & development products
 - · Veterinary products
- In the event refrigeration is used on site, there can be liability associated with the release of 'coolants' such as anhydrous ammonia.

- Environmental liability assumed in acquisition and divestiture of property.
- Large parcels of undeveloped property tend to have fewer environmental issues. As a result, many times there are poor or inadequate records of activity on those lands. Phase I environmental assessments are cursory reviews of the site with a "walk-through" of the property to physically identify issues. Environmental reports might not identify illegal or "midnight" dumping of waste or materials on these lands. The contamination may only be revealed during development.
- Select a quality firm to perform the Phase I assessment.
 The Phase I is the most minimal in scope when it comes
 to environmental assessments, and quality assurance is
 important for an accurate risk profile of the property.
- Residual contamination of soil / groundwater from the use of hazardous and non-hazardous materials. Simple, non-reportable spills that go unaddressed can lead to

CONTACT



EXPOSURES (CONT'D)

greater first- and third-party environmental claims.

- Air emissions from various processes painting and plating lines, ovens, boilers and reactors – including:
- Volatile Organic Compounds (VOCs)
- · Fuel, gases
- Improperly maintained PCB-containing equipment and transformers. PCBs tend to be fairly immobile in soil; this may lead to surface contamination at and beyond property boundaries.
- Improper housekeeping and preventive maintenance resulting in residual contamination from spent solvents, chemical reactants, biological agents, etc.
- Malfunctioning pollution control equipment, leading to untreated discharge of air emissions or wastewater.
- Inadequate underground and aboveground tank inventory and / or management programs can lead to groundwater contamination.
- Inadequate or improper waste / raw materials storage / handling practices.
- Improper storage of incompatible materials may lead to on-site releases and / or potential explosion.
- Improper treatment or disposal of sludge from wastewater and water treatment operations.
- Natural Resource Damages, resulting in substantial costs for state- and federal- mandated cleanup requirements and potential fines.
- Exposed asbestos and lead paint in on- site structures.
- Release of product from pipelines, resulting in soil and groundwater contamination.
- Improper storage, resulting in release of:
 - Acids / alkalines
 - Compressed gases, including cyanide and hydrogen chloride
 - · Diesel fuel and lubricant oils
 - Flammable paints and solvents

TRANSPORTATION EXPOSURES

- Inadvertent transport and subsequent disposal of unknown contaminated soil from onsite activities.
- Loading and unloading of product from rail cars, trucks, etc.
- Spills of contents (e.g., fuel, product, equipment maintenance fluids, process materials, etc.) during transport.
- Resulting pollution from collisions with various structures (e.g., pole mounted transformers, aboveground tanks, etc.)
- Fuel / oil spills / leaks from vandalism during transport.

DISPOSAL EXPOSURES

- Inadequate disposal of waste from processes such as chemical blending, fermentation and distillation:
 - · Biological agents
 - · Spent solvents
 - · Various chemicals
- Clean up and liability associated with the disposal of waste / materials at disposal facilities or recyclers.
 This may expose the organization to Superfund liability.
- Improper "disposal" or sale of production by-products.



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PHARMACEUTICAL INDUSTRY

Name of Organization:		
Lasts Updated:		

SAMPLE ENVIRONMENTAL RISK PROFILE

Below is the start of a sample ERP for Pharmaceutical Industry. A complete ERP can be added to provide a detailed profile: reference documents, website links, details on prior claims / incidents and the organization's response.

A complete ERP can be used to help risk and insurance managers better identify, manage, reduce and even eliminate the organization's exposures to environmental liability and the related costs.

EXPOSURE	IMPACT ON ORGANIZATION	RESPONSIBILITY	RISK MANAGEMENT TECHNIQUE	PRIOR INCIDENTS
OPERATIONAL EXPOSURES: 1.Pre-existing environmental conditions on acquired property. 2.Potential impact to soil and groundwater from current operations.	Costs associated with developmental delays, remediation, etc. Liability associated with contamination as the current owner of property. Possible Superfund liability.	Site manager, legal counsel, environmental manager, or risk manager.	Self perform environmental data searches on designated EPA websites to identify potential concerns. Hire environmental data firm to collect information on the property. Conduct an environmental assessment Environmental indemnities in contract of sale. Environmental insurance to protect from liability associated with on- and off-site contamination.	None
TRANSPORTATION EXPOSURES:				
DISPOSAL EXPOSURES:				

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