

An Industry's Guidelines for Risk Assessment

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In the absence of a consensus on absolute limits of risk, it is useful to have a goal-oriented risk assessment framework for decision making and response resource allocation. A four-step process is in use at Shell to evaluate risks and define appropriate responses. The steps are: (1) Hazard Identification, (2) Hazard Evaluation, (3) Risk Evaluation, and (4) Risk Response. The first three steps amount to making a "risk assessment," and the fourth step adds a response definition. A risk classification system setting high, low and insignificant categories for risk reflecting unacceptable, variously acceptable and acceptable regions respectively are defined, and companion levels of response action are presented. An overview of a site evaluation experience in California is outlined.

Risk assessment is a difficult problem area being addressed by industry and regulatory agencies today. I have found in my professional experience in the oil and chemical industry, that when faced with solving difficult problems, solutions generally resulted by taking logical and disciplined approaches to resolve uncertainties. We at Shell have developed and are using guidelines for risk assessment which are allowing us to analyze risks and identify reasonable responses. The use of these systematic procedures have improved our confidence in the decisions we must make. In responding to risk situations, our confidence is built on knowing that the responses are directionally correct and are achieving our overall goal to reduce risk.

Of late, I have been disappointed by the consensus opinion which appears to be growing regarding dealing with risk assessments. From information in the media and discussions with contemporaries and agency representatives, I detect an opinion that suggests society is not ready to deal systematically with

0097-6156/82/0204-0045\$06.00/0
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assessing risk. In my view, those who support this claim are as remiss at that extreme as those who would now place total faith in seemingly highly precise methodologies for extrapolations and risk assessments. Additionally, the opinion follows that we are not ready to translate current risk assessment understanding into regulatory programs being implemented.

I don't think we at Shell agree with either opinion, or are a part of any consensus embracing these opinions. We will be disappointed, I'm sure, if the implementation of either the Resource Conservation and Recovery Act (RCRA) or the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) programs proceed without there being incorporated at least some regulatory allowances for assessing actual risks. The risks posed by various hazardous waste handling activities must be assessed when judgments on their acceptability are made, such as during the permitting process. I am suggesting that the ability to assess actual risks exists, and it should be considered when (1) setting regulatory requirements, (2) when establishing facility performance standards, or (3) when defining remedial activities.

We fully recognize that many areas of uncertainty are confronted when conducting risk assessments. These include the lack of generally accepted specific assessment techniques. Furthermore, even when risk is assessed there is a lack of a consensus on the absolute limits of acceptable risks. We do feel, however, that there are systematic approaches that can and are being used and, at the minimum, they are directionally correct and can serve as a conceptual framework for regulatory program development.

Shell Risk Assessment Procedure

I will outline very briefly for you the guidelines, process and procedures used at Shell for risk assessment and risk response (1), (2). I will focus my comments on how we are beginning to deal, for example, with decisions concerning the acceptability of operating existing hazardous waste disposal facilities or when considering new waste handling facilities.

The step-wise evaluation and decision process can also be used in assessing the environmental risks posed by abandoned hazardous waste disposal sites. I will also briefly describe our experience with a site in a southern California community.

Our Risk Assessment Procedure has grown out of a continuing need to deal with balancing all the aspects of health and environmental risks with all other pertinent elements in our oil and chemical business activities. The decisions we must make to deal appropriately with risk are necessarily an important consideration in pursuing our overall business plan.

In many cases, we must take action and make decisions prior to regulations being issued which deal with risk in specific areas. By necessity then, we need and use a system that reflects our corporate environmental goals and also allows guiding the

allocation of the limited resources available to reach those goals.

In a sense, we can say we have developed a system to assess environmental risk situations and are responding to those assessments with decisions reached in a deliberate and disciplined manner. The confidence we have in the system is built on the premise that we know it is directionally correct with its overall objective being to reduce risks. Moreover, the response decisions called for in the process result from evaluating all the available scientific information along with all the pertinent values and judgments that can be brought to bear.

Overall, the major premise for our approach is a directional orientation toward risk reduction. The evaluation procedure used follows a four-step process which considers first Hazard Identification; second, Hazard Evaluation; third, Risk Evaluation; and fourth, Risk Response. To avoid any misunderstanding of terms, the combined activities of the first three steps can be considered as what is commonly referred to as making a "Risk Assessment." The fourth step, Risk Response, necessarily must follow when the process is used to make practical decisions.

I will now give an overview discussion identifying the general information needs and the specific decisions called for at each step. I will use as the example case, evaluating a hazardous waste disposal site. Also, I will discuss the application of the process to an actual site being evaluated in California.

Hazard Identification

As is typical in regulatory matters, understanding the definitions of the terms used is very important. First, in the broadest sense, hazard means the potential to do harm, or in other words, the potential to cause an adverse effect.

In a waste disposal site evaluation, the hazard identification step will involve collecting and validating all recorded and other information on the nature and properties of the wastes actually in a site. The purpose is to determine whether a hazardous situation actually exists. Stated simply, is there a potential for harm to health and the environment when considering the materials present?

The type of data gathered will include all pertinent information on (1) the inventory of the wastes disposed of at the site, (2) the composition of those wastes, (3) the physical and chemical properties such as persistence of compounds and their solubilities, (4) the biological properties such as toxicity, and (5) the potential interaction of wastes and degradation products.

The decision called for at this point in the process centers on confirming that, from the qualitative data gathered, a potential for an adverse effect has or has not been identified. If no hazard exists, further action is not warranted. If the potential for an adverse effect is evident, the process requires proceeding to the next step - Hazard Evaluation.

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Hazard Evaluation

The hazard evaluation step involves determining the extent or scope of the potential adverse effects from the hazards identified in step one. The evaluation effort now progresses to include analyzing and describing both qualitatively and quantitatively the characteristics which might cause the wastes to be hazardous and to providing the means for determining in step three, the risks involved under the disposal circumstances specific to the site being studied. These means may include gathering pertinent information from laboratory and other studies on the toxicological properties of the array of constituents in the site. Also pertinent would be the range of responses to those constituents under the various stated, not actual, levels and types of exposures along with reviewing inter-species translation relationships and the means to extrapolate these to actual conditions.

With the focus on the actual quantities of wastes identified in the site inventory, appropriate field sampling and analysis must be undertaken to verify that the identified hazards actually exist. If a hazard has been identified and the potential for causing adverse effects confirmed, after considering both the qualitative and quantitative dimensions of the situation, the process requires proceeding to the next step - Risk Evaluation.

Risk Evaluation

Risk evaluation in the assessment process focuses on weighing the health and environmental threats posed by an identified hazard. First, the possibility and probability that a person will actually experience an adverse effect as a result of the existence of the environmental hazard and exposure to it must be weighed; and, secondly, the number of persons who might be exposed must be considered.

In the stepwise process, the risk evaluation combines the results of the second step, hazard evaluation, with any information on actual exposure possibilities, including evaluating exposure sources, levels, frequencies, types and routes. The assessment effort involves interpreting the field verified data from the perspective of determining what the actual risk level to humans and the environment is in the real world circumstances posed by the activity being evaluated.

In the case of a hazardous waste disposal site, the geohydrologic setting characteristics must now be carefully considered to assess the existence of subsurface exposure routes. Also, the potential for exposure from air emissions and surface runoff must be quantified where possible. Overall, the significant factors would include: (1) evaluating the volatility of the wastes which could lead to short- and long-term exposure to air

emissions, (2) considering the long-term solubility of the wastes in waters from either rainfall or surface runoff, (3) considering the continuing potential for surface water contact, (4) reviewing the rainfall rates and rainfall flow paths as to their ability to support their contribution to continued exposure, (5) identifying the groundwater contamination potential and migration paths, (6) identifying groundwater uses, and (7) appraising population exposure by considering proximity and number.

If the risk evaluation step shows that a significant potential for adverse effects exists, the stepwise process calls for developing an appropriate response. Determining the appropriateness of a response implies having a basis to vary the response. Providing that basis is the end product of the risk evaluation step. It involves classifying the risk as being high, low or insignificant so that the appropriate response can be developed.

Before discussing how risks are classified, I would like to emphasize that the hazard identification, hazard evaluation, and risk evaluation steps are purposely kept free, as much as possible, of value judgments. Credible risk evaluations necessarily require using the best scientific input, theory, acumen and judgments. In the fourth step, value judgments come into play to assist in developing risk responses reflecting those societal judgments that bear on the situation being evaluated.

To classify risks, a system or framework for classification must be agreed upon. In a perfect world, a societal consensus on levels of "risk acceptability" would be at hand and be straightforward in how it would be applied in each situation being evaluated. However, in the real world there is no consensus, and we can only evaluate and then define the ranges of risks posed in actual situations and then judge them for their acceptability to society.

Within Shell, when taking actions beyond those required by law, we use the concept of risk regions or risk classifications. The objective of our classification scheme is twofold; first, to provide guidance for the allocation of resources such that the most serious risks are handled first; and second, to identify those situations where allocating resources is not warranted since the risk is judged to be insignificant.

Our system, therefore, distinguishes three classifications of risk: high, low, and insignificant. One might argue that a medium risk region exists. At this time, considering a medium risk region would only add an unrealistic aura of precision to the system. We recognized at the outset that the tools available to us in our classification scheme are blunt.

Definition of the boundaries between the risk regions can be precise by choice; however, there are no established criteria for boundary setting and, at this time, only guidelines for boundary selection can be offered (1). The range of choices might include (1) reasonable performance goals for best technology control equipment when actual exposure levels from existing facilities is

assessed, (2) the feasibility of controlling exposures, and (3) a desirable industry or activity performance goal.

While the framework for risk regions is precise, the uncertainties emerge when real world imprecise evaluations of risk - recognizing the bluntness of our tools - are measured by the precise yardsticks. Nevertheless, when considering risk classifications from a societal viewpoint, one can have confidence and logically classify high risk regions as being regions of "unacceptable risk." The low risk region might similarly be labeled as "variously acceptable" with the third region referred to as "insignificant risk." Consistent with that classification scheme, one could define a parallel series of appropriate responses.

Risk Response

Risk response involves additional difficulties. Defining responses includes making comparisons with other examples of risks society takes, including their view on the seriousness of the risk and the perceived benefits from taking that risk. From the process of combining the scientific information available with the pertinent value judgments, decisions can be made as to what actions are required and justified as appropriate response to the risk posed.

When a risk assessment shows a "high risk" situation, this would be judged unacceptable and require a response to abate the risk and move it downward toward the "low risk" or "variously acceptable" region.

Similarly, an "insignificant risk" classification is judged as defining those situations which do not justify or warrant the allocation of resources for further risk reduction. I must emphasize at this point that the "insignificant" classification is not equivalent to an absolute "zero risk."

The "low risk" or "variously acceptable" region under this labeling scheme would then, by difference between high and insignificant, identify those situations where balancing decisions which consider risks, benefits and justification must be made for prioritizing the application of critical resources.

The exercise of balancing risks and benefits in the "low risk" region is clearly an area where regulatory guidance should emphasize the importance of relating risk reduction to costs, benefits and alternative risks. This "low risk" or "variously acceptable" region is the area where costs to reduce risk should be justified and alternatives considered. For just as zero risk is not generally attainable, very little real progress toward our goal would be reached if we attempted to shift all "variously acceptable" risks downward.

Regardless of the absence of a governmental policy establishing absolute risk limits or boundaries of acceptability, risk response decisions must be made in many industrial situations. We have found that coupling disciplined risk assessment procedures

with the risk region classification techniques yields appropriate response actions, and the process has proven to be a practical tool to deal with these inherently imprecise situations.

Using the risk assessment and classification approach in evaluating waste disposal site situations should likewise allow making practical decisions by coupling risk levels with appropriate remedial responses. The stepwise decision process should also be useful in evaluating the scope of risks posed by abandoned disposal sites. If the risk assessment process leads to the conclusion that a disposal site is, indeed, posing a significant threat to health or the environment, appropriate levels and types of responses can be defined. By considering all the quantifiable factors, the identified uncertainties, and the geohydrologic predictions and projections specific to each site, supportable practical response decisions can be made. If a "high risk" classification is supportable, the response action to reduce that particular risk is progressed without comparison to other risks. If an "insignificant risk" classification is given, no action is required solely to reduce risk to health or the environment.

A circumstance worth mentioning at this point is the response appropriate to deal with nuisance and esthetic issues such as odor or noise when no hazard can be identified. A risk classification of "insignificant," with respect to health or the environment, would likely be selected and no response justified in the case of a disposal site evaluation where only odor is the problem. In these instances, appropriate responses should be developed using a process which reflects the economic, social and political impacts of the problem rather than the assessment process being described which has been developed to deal with hazards to health.

In disposal sites with identified hazards, the more difficult and involved decisions will have to be faced when the circumstances result in selecting the "low risk" classification. Since total cost/benefit considerations appropriately come into play -- for here we hope to achieve the greatest reduction in risks for each dollar spent -- the response actions can vary accordingly. While risk reduction is the overall objective, reducing the selected risk level into the "insignificant" classification is not automatically the optimum solution since it may require inordinate and excessive resource utilization.

California Site Study

The evaluation of an actual disposal site in southern California has been following a pattern of events that, in ways, fits the process I have been discussing. I would like to share with you the highlights of this evaluation.

Shell is one of a number of participants in an effort to define and resolve the problems posed by a disposal site in an established community. The site was permitted during the 1940's, and used for disposal of acidic materials from petroleum refineries in the area. It is in a developed residential area.

As might be expected, when the site was identified and some of the circumstances surrounding its past use were exposed in the media, the reaction of many was to expect an immediate clean-up. Relating this reaction to the step-wise procedure I have been discussing, some jumped ahead to step four - Risk Response - and called for an immediate excavation without having considered steps one, two or three. Calling for immediate clean-up is equivalent to classifying the situation as one posing a high risk. Doing so can only be conjecture when only limited and qualitative data is at hand. This reaction was, of course, premature and disregarded completely such functions as identifying and evaluating the risk associated with excavation.

A better approach to resolve community concern is to move forward and follow the systematic procedure to first identify the hazard, evaluate its scope, assess the risks posed, and then develop an appropriate response.

At the California site, an early preliminary evaluation by federal, state, and local agencies was made to identify the nature of the materials in the site and the potential for an adverse effect. Then, with industry participation, a plan was followed to develop and then implement a detailed and comprehensive site evaluation.

The data from the evaluation effort will allow making a supportable decision on the hazards posed by the site. Also from the data gathered during the study, predictions and projections can be made as to the scope of both the current and future risks posed by the site. In addition, this process will provide information necessary to understand the risks associated with the specific remedial measures available and under consideration.

From consultations with the agencies involved, the community, and with the industrial participants, the risks posed by the site should be classifiable and appropriate response and remedial measures agreed upon. We have confidence that this scenario will be followed to reach a satisfactory resolution of the problems associated with this site.

Summary

I trust that you will agree that the use of a step-wise process for risk assessment and response development and the companion concept of using risk regions or risk classification, offers a framework for practical decision making.

Making the effort at this time to define boundaries between high, low and insignificant risks in risk assessment situations, is not preempting any ultimate societal judgement. Eventually governmental policy will likely define the risk boundary limits. In the interim, using systems and approaches that are directionally oriented to reduce risk can serve as a base for establishing the logical framework that facilitates practical decision making.

It would appear to be worthwhile to support efforts to develop risk assessment approaches along the lines I have discussed rather than join a consensus saying that it cannot be done, or in supporting selecting mathematical models which arbitrarily define hazards and risks.

We solicit your consideration in developing a broader consensus which supports the premise that a deliberate, disciplined, stepwise approach to making risk assessments is available for practical application in disposal site evaluations.

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RECEIVED June 16, 1982.